MEDICARE QUALITY OF CARE, AND OUTCOMES AND EFFECTIVENESS RESEARCH

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES

ONE HUNDRED SECOND CONGRESS

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MEDICARE QUALITY OF CARE, AND OUTCOMES AND EFFECTIVENESS RESEARCH

TUESDAY, APRIL 30, 1991

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC

The subcommittee met, pursuant to notice, at 10:43 a.m., in room 1100, Longworth House Office Building, Hon. Fortney Pete Stark (chairman of the subcommittee) presiding.

[The press release announcing the hearing follows:]

FOR IMMEDIATE RELEASE
THURSDAY, APRIL 25, 1991

PRESS RELEASE #9
SUBCOMMITTEE ON HEALTH
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THE HONORABLE PETE STARK (D., CALIF.), CHAIRMAN, SUBCOMMITTEE ON HEALTH, COMMITTEE ON WAYS AND MEANS, U.S. HOUSE OF REPRESENTATIVES, ANNOUNCES A HEARING ON MEDICARE QUALITY OF CARE, AND OUTCOMES AND EFFECTIVENESS RESEARCH

The Honorable Pete Stark (D., Calif.), Chairman, Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives, announced today that the Subcommittee will hold a hearing on Medicare quality of care, and research on outcomes and effectiveness of care. The hearing will be held on Tuesday, April 30, 1991, beginning at 10:30 a.m., in room 1100 Longworth House Office Building.

In announcing the hearing, Chairman Stark said, "Many Medicare patients receive the care they don't need while others don't receive the care they should. This hearing will provide an opportunity to review the progress made over the last two years in assuring that all patients receive care that is both effective and of high quality."

I would like to commend my colleague, Mr. Gradison, who has shown a strong and continuing interest in this important issue."

Oral testimony will be heard from **invited witnesses only**. However, any individual or organization may submit a written statement for consideration by the Subcommittee and for inclusion in the printed record of the hearing.

BACKGROUND

There are wide variations in medical practice. For example, residents of New Haven, Connecticut, are twice as likely to undergo coronary artery by-pass surgery than residents of Boston, Massachusetts. In one community in Maine, nearly 70 percent of women have had a hysterectomy by age 70, while the rate is only 20 percent in another Maine community. In one community in Vermont, only 8 percent of children have had a tonsillectomy while nearly 70 percent in another community have had tonsillectomies.

Research has also shown substantial variation in the appropriateness of medical care that is provided. One study examined the appropriateness of three common procedures performed on Medicare patients: carotid endarterectomies, coronary angiographies, and upper gastrointestinal endoscopies. Over 25 percent of these procedures were performed for inappropriate or equivocal reasons.

The Omnibus Budget Reconciliation Act of 1989 (OBRA 89) established a program of research on the quality and effectiveness of medical care. This program is contained within a new agency of the Public Health Service (PHS), the Agency for Health Care Policy and Research (AHCPR). The responsibilities of AHCPR include: the development of practice guidelines and standards; research, demonstration projects, evaluations, and training; and dissemination of information on the effectiveness, efficiency and quality of health care.

(MORE)

The Secretary of Health and Human Services is required to develop guidelines for the treatment or management of at least three conditions that account for significant Medicare expenditures by January 1, 1991. These guidelines have not yet been completed. The Secretary is then required to implement the use of these guidelines or standards by physicians, and to evaluate the impact on the care of Medicare patients.

OBRA 89 also provides for the development of standards for data bases on medical care services and outcomes that could support research on the outcomes and effectiveness of care. H.R. 1565, introduced by the Honorable Nancy Johnson (R., Conn.) and the Honorable Rod Chandler (R., Wash.), et al, provides for the standardization and development of hospital electronic data systems that could be used to support outcomes and effectiveness research, as well as quality monitoring.

OBRA 89 authorized funding for the AHCPR from three sources: the Medicare trust funds, general revenues, and 40 percent of the amount authorized for evaluations in the PHS, the so-called "evaluation set-aside."

For fiscal year 1992, OBRA 89 authorized $110 million from the Medicare trust funds and $75 million from general revenues. The evaluation set-aside accounts for an additional $50 million in fiscal year 1992.

Expenditures for the AHCPR were $97 million in fiscal year 1990 and $115 million in fiscal year 1991. The Administration's budget includes a proposal to increase spending for activities within the AHCPR by $7 million, for a total of $122 million in fiscal year 1992.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

For those who wish to file a written statement for the printed record of the hearing, six (6) copies are required and must be submitted by the close of business on Wednesday, May 8, 1991, to Robert J. Leonard, Chief Counsel, Committee on Ways and Means, U.S. House of Representatives, 1102 Longworth House Office Building, Washington, D.C. 20515. An additional supply of statements may be furnished for distribution to the press and public if supplied to the Subcommittee office, 1114 Longworth House Office Building, before the hearing begins.

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will **not** be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All statements and any accompanying exhibits for printing must be typed in single space on legal-size paper and may not exceed a total of 10 pages.
2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.
3. Statements must contain the name and capacity in which the witness will appear or, for written comments, the name and capacity of the person submitting the statement, as well as any clients or persons, or any organization for whom the witness appears or for whom the statement is submitted.
4. A supplemental sheet must accompany each statement listing the name, full address, a telephone number where the witness or the designated representative may be reached and a topical outline or summary of the comments and recommendations in the full statement. This supplemental sheet will not be included in the printed record.

The above restrictions and limitations apply only to material being submitted for printing. Statements and exhibits or supplementary material submitted solely for distribution to the Members, the press and public during the course of a public hearing, may be submitted in other forms.

Chairman STARK. Good morning. The Subcommittee on Health of the Committee on Ways and Means will begin its hearing this morning on Medicare quality of care, and outcomes and effectiveness research, and practice guidelines program enacted in the OBRA 1989 Act.

The part B program of Medicare is one of the fastest growing segments in the Federal budget, expenditures for which have consistently grown at rates from 10 to 13 percent a year. About half of this growth in expenditures has been due to increases in volume of services provided per beneficiary.

I would note that it is rather hard to increase the volume per beneficiary in cataract surgery or gall bladder removals, seeing as there is a limited supply of those for physicians to ply their trade. But there are an awful lot of tests and other types of procedures that can be performed.

Substantial evidence suggests that many patients are receiving health care that is ineffective. For example, research at the Rand Corp. has shown that 25 percent of three common procedures are performed based on indications that are either inappropriate or questionable at best. Other research also has shown wide variations in the patterns of care provided in similar communities. Patients in Boston, for example, are half as likely to have coronary bypass surgery as patients in New Haven, CT.

Based on this, provisions in OBRA 1989 provided for the establishment of a significant Federal research program intended to study the appropriateness of medical procedures, develop practice guidelines describing appropriate care, and encourage physicians to modify their medical practices.

OBRA 1989 also created the Agency for Health Care Policy and Research to coordinate this effort.

Controlling growth in the volume of services and ensuring that patients receive appropriate care should be among our highest priorities. Today's hearing provides this subcommittee with an opportunity to review the progress that has been made since the enactment of OBRA 1989.

I would like to commend my colleague, the gentleman from Ohio, Mr. Gradison, for his long-standing interest in this important area and for his leadership on this issue during consideration of OBRA 1989.

I would also like to thank the witnesses who are testifying today for their contributions to this hearing. These problems are complex, and I would like to assure the witnesses that their comments will help the subcommittee to understand these issues.

I think also it would be fair, as we question the witnesses and try and expand on their testimony, that the Chair has a concern that we identify the proper place of effectiveness and outcomes research in the scheme of things. I do not think that outcomes and effectiveness-research can necessarily save us any money. I think it can help a physician decide which procedure might be better with some more empirical evidence, but I don't think that it can ever suggest to a physician that he or she limit or deny a patient a procedure.

I do think that caps, for example, as an alternative can be better applied at a microlevel with some better understanding of which procedure might be the best way to save money. I have some con-

cern that this is being treated as a way to save money, and I am not sure that that is necessarily the case. I hope some of the witnesses can enlighten me.

I would like to recognize any of the other members who may have a statement. Mr. Gradison?

Mr. GRADISON. Thank you, Mr. Chairman. Thanks for your kind remarks. I have been interested, as many of my colleagues in both Houses have been, in this subject for a long time and have watched with great admiration the superb job that Dr. Clinton has done in getting this activity off on the right track. I am happy to hear that we may look forward to his continuing leadership for some time to come, and I think that is a very encouraging development.

With regard to the matter you just mentioned, Mr. Chairman, certainly my support of this has not been conditioned on the assumption that we are going to save any money. I felt that would be great if it happens, but I think there are very important reasons for doing this, whether it saves money or not. Perhaps that is consistent with where we are on it.

Chairman STARK. If the gentleman would yield. It is entirely consistent. I like to think of it as a cost-savings tool which would be heading us somewhat in the wrong direction. I think there are much more important considerations and results that can come out of this.

Mr. GRADISON. One thing that struck me in the testimony we received last week was the fact that, to some extent, these guidelines are already in use in the private sector in the development of algorithms, that are used for the review of various surgical procedures that require advance approval.

We will hear more about this, I suppose, in the first panel. I was struck by the information given to us that, based upon some of the Rand work done back in the early 1980's, there were quite a few million people in this country not covered by plans where these reviews were being made. In addition, the denial rate was running in the 10 to 12 percent area with regard to, as I recall it, 35 high-priced procedures which were being reviewed by one of the organizations that is active in the field. I don't know if that is the wave of the future, but I hadn't realized that this notion had gotten this far beyond the drawing board as perhaps it has. I was very encouraged by that.

Thank you, Mr. Chairman.

Chairman STARK. Mrs. Johnson.

Mrs. JOHNSON. Thank you, Mr. Chairman. Just very briefly, I consider this a very important hearing, and I look forward to the comments of the panelists.

Certainly we do have to do something about spiraling health care costs. I would hope, frankly, that one way we would save money is through better understanding of what works and what doesn't work, and that the reduction in volume will enable us to achieve what would be in both the patients' and the Government's interest. I look forward to your comments.

Thank you, Mr. Chairman.

Chairman STARK. Thank you.

Our first witnesses this morning are Dr. Gail Wilensky, the Administrator of the Health Care Financing Administration; and Dr. Jar-

rett Clinton, the Administrator of the Agency for Health Care Policy and Research.

Welcome to the subcommittee. Welcome back, Gail. As for all of our witnesses testifying today, written testimony without objection will be made part of the permanent record, and you may summarize or expand on your testimony in any manner with which you are comfortable.

Gail, do you want to lead off?

STATEMENT OF GAIL R. WILENSKY, PH.D., ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Ms. WILENSKY. Thank you.

Mr. Chairman and members of the subcommittee, I am pleased to appear with Dr. Clinton to discuss the Department's Medical Treatment Effectiveness Program. I would like to join him in thanking the subcommittee for its work on this important initiative.

I am proud of the Health Care Financing Administration's involvement in this effective program because I believe it holds great promise to help transform medical practice.

I see effectiveness-research and practice guidelines as providing a framework for an ongoing dialogue with the medical community. HCFA and the Agency for Health Care Policy and Research will provide medical professionals with scientific information they need in order to make wise clinical choices. We will learn from the professionals and from analyzing the results of their practice.

While Dr. Clinton's agency quite appropriately has the lead, HCFA is active in effectiveness work as well. Our working relationship with the Agency for Health Care Policy and Research is an excellent one. We are enhancing our data systems so that they are more useful for outcomes research. We are radically transforming our peer review organization program, and we are conducting some effectiveness studies that complement those that the Agency for Health Care Policy and Research has funded.

More importantly, we are working through the PRO's to place information about what works in health care in the hands of medical professionals. We hope they will use the information to improve the quality of care for Medicare beneficiaries.

Over the next decade, we plan to move our PRO Program away from the current manual review of hospital records. We want PRO's to use large databases of clinical information to identify patterns of inappropriate utilization and poor outcomes. We want them to modify inappropriate behavior and improve medical practice by sharing information on patterns of care and outcomes with the local medical community.

One tool for transforming the PRO Program will be a state-of-the-art computer system known as the Uniform Clinical Data Set, or UCDS. PRO's will enter clinical data from each medical record into the UCDS. It will subject the data to a series of decision rules or computerized quality screens. The screens will identify cases needing review by a PRO physician.

We expect the practice guidelines developed by the Agency for Health Care Policy and Research to be adapted to serve as UCDS quality screens. The data in the UCDS will become a rich epidemiologic database. PRO's will use it to target their reviews in interventions to areas with poor patient outcomes.

PRO's have been convening local physician study groups to begin our dialogue with the medical community. In the future, we expect PRO's to use this approach to disseminate new practice guidelines and research findings, and to draw local physicians' attention to concerns about local patterns of outcomes or care.

By the end of this year, HCFA will have restructured its claims-data systems to create a single large national claims history database of information about all Medicare fee-for-service services. Our proposed Current Beneficiary Survey will tell us about elderly patients' health and the way they function on a day-to-day basis. These changes will make our data systems more useful for effectiveness research.

HCFA is conducting more than 20 of its own effectiveness-research projects. For example, we are linking our data to registries maintained by the National Cancer Institute to determine the patterns of care, comorbidities, and outcomes of different types of cancer.

HCFA and the Agency for Health Care Policy and Research cooperate on research and on a number of other fronts. HCFA develops and supplies data needed by Dr. Clinton's patient outcomes research teams. We are jointly sponsoring a study to track Medicare patients following their discharge from the hospital, and we are collaborating on the design of a potential Medicare beneficiary health status registry which would collect medical histories for some beneficiaries entering the Medicare program.

Finally, our PRO's will participate in a study to develop and evaluate review criteria based on the agency's practice guidelines, and we will disseminate the guidelines.

Effectiveness research and practice guidelines have the potential to substantially improve the quality of health care in this country and the value we get for our health care dollar. They will also provide a more appropriate standard of care for use in medical liability cases. However, we do not expect to make wholesale changes in our coverage policies when we receive them.

I believe it is important that the medical community fully understand practice guidelines and adopt them voluntarily. We should not expect guidelines to work miracles in restraining U.S. health care costs. One hypothetical guideline might, indeed, save us money by recommending that medical treatment would be more appropriate for some candidates for coronary bypass surgery. But another guideline might indicate that some expensive service or procedure is underutilized. So providing more appropriate care in that case could increase costs.

I emphasize that our dialog with the health care community on what works in medical care will be a continuing process. The quality of patient care, however, should improve with each of these interchanges. Medical practice will not be transformed overnight. It is important for us to retain the support of many different groups of health care professionals, institutional providers, and

consumer groups now committed to the pursuit of effectiveness in medical care.

I look forward to continuing to work with the Congress, with the Agency for Health Care Policy and Research, and others in the Department, and with health care and patient communities to bring about this transformation of medical practice.

Thank you, and I would be happy to answer any questions you may have.

[The prepared statement follows:]

STATEMENT OF

GAIL R. WILENSKY, PH.D.

ADMINISTRATOR

HEALTH CARE FINANCING ADMINISTRATION

Mr. Chairman and Members of the Subcommittee:

I am pleased to appear with Dr. Clinton here today to discuss the Department of Health and Human Services' Medical Treatment Effectiveness Program (MEDTEP). I would like to join him in thanking the subcommittee for its work in furthering this important initiative.

I am proud of the Health Care Financing Administration's involvement in MEDTEP, because I believe that this effectiveness initiative holds great promise to help transform medical practice.

Clinicians across the country should have better access to scientific findings about the benefits and risks of various treatments in guiding their patients' care -- and they will, under the MEDTEP program. Patients, as well, need opportunities to become better educated about the findings on risks and benefits and to be better equipped to make informed choices about their own health care, and we plan to provide those opportunities.

Personally, I see effectiveness research and practice guidelines as providing a framework for developing an ongoing dialogue with the medical community. AHCPR and HCFA will provide medical professionals with some important scientific information they need in order to make wise clinical choices. We will also learn from the professionals, and from analyzing the results of their practice. Their feedback, combined with our analysis, will tell us whether the guidelines were effective in improving patients' outcomes -- information that will be used in refining the guidelines and targeting research.

I hope to build on the foundation for the Effectiveness Initiative that was laid here in our agency by my predecessor, Dr. William Roper. In July 1988, as you know, Mr. Chairman, Dr. Roper announced that HCFA would begin a new initiative to determine what works in medical practice in order to foster clinically effective medical care.

While the lead in the effectiveness initiative now rests, quite appropriately, with the Agency for Health Care Policy and Research, I believe it is important for HCFA to continue to play a key role. We have an excellent working relationship with AHCPR, and I serve with Dr. Mason and Dr. Clinton on the Intradepartmental Committee for the Medical Treatment Effectiveness Program, which establishes long-term goals, research priorities and annual budget levels for MEDTEP activities.

I will ensure that HCFA continues to pursue and expand many of the research activities begun during Dr. Roper's tenure. We are enhancing our data systems so that they are more useful for outcomes research. We are radically transforming our Utilization and Quality Control Peer Review Organization (PRO) program to fit the needs of our beneficiaries in the 21st Century, by basing our quality assurance mechanisms on epidemiologic analysis.

Most importantly, I believe, we are working through the PROs to bring together information about what works in health care and about existing patterns of care, and place it in the hands of medical professionals. We hope those professionals will learn from the information we provide, and will use it to improve the quality of care for Medicare beneficiaries.

The PRO Program

As you know, PROs are charged with ensuring that health care services delivered to Medicare beneficiaries are necessary, appropriate, and meet standards of quality.

Over the next decade, we plan to move the PRO program away from the current manual, judgmental and variable review of hospital records, toward using large databases of clinical information to identify patterns of inappropriate utilization and poor outcomes.

We plan to move the program from penalizing providers for single instances of poor care, toward modifying inappropriate behavior and improving medical practice by sharing information on patterns of care and outcomes with the local medical community. This transformation incorporates the essence of the recommendations of the recent Institute of Medicine report, "A Strategy for Quality Assurance in Medicare."

One of HCFA's important tools for transforming the PRO program will be a state-of-the-art computer system known as the Uniform Clinical Data Set (UCDS). UCDS will permit us to gather, develop, and analyze extensive clinical data.

In the next few years of the transition to a truly outcome-based program, PROs will abstract up to 1600 relevant data elements into the UCDS from each medical record under review. The UCDS will then subject the abstracted clinical data to a series of decision rules that serve as computerized quality screens, in order to identify cases needing further review by a PRO physician.

The computerized quality screens were initially constructed and reviewed by expert panels of physicians, and they have been pilot-tested by the PROs. We expect the screens to be constantly reviewed, refined and updated with advances in medical care and in knowledge of which practices result in the best outcomes. AHCPR's research will certainly be a major source of information for these updates. In addition, we expect AHCPR-developed practice guidelines to be adapted to serve as UCDS quality screens.

In the longer term, the clinical data abstracted by the PRO will allow the PROs to evaluate patterns of care and patterns of outcomes, adjusted for the condition of patients. We plan to equip PROs with the tools to perform this analysis.

These data will also provide a rich epidemiologic database, which we expect to be fertile ground for research into outcomes, effectiveness and the quality of care. By linking the UCDS database to currently available Medicare data, we will be able to examine the pre- and post-hospitalization care provided to a patient whose hospital record is included in the UCDS file.

This epidemiologic approach will enable PROs to target their case-by-case reviews and educational interventions to specific geographic areas, providers or practitioners. They will look for areas where patients' outcomes are markedly worse than would have been expected for patients with those characteristics.

Development of HCFA Data

The UCDS is but one example of HCFA's efforts to make its data systems more useful for effectiveness research.

HCFA's program data on its 34 million beneficiaries already comprise the largest population, provider and medical claims databases in the country. And by the end of this year, HCFA will have restructured its claims data systems to create a single large National Claims History Database, which will contain information about all Medicare fee-for-service services. It will be used for monitoring HCFA programs and research on the effectiveness of care.

Using the National Claims History, researchers will be able to information about the care provided in all types of settings and about adverse patient outcomes such as heart attacks, strokes, infections and hospital readmissions after specific treatments. The existing Health Insurance Master File will complement the National Claims History by providing demographic information about beneficiaries and their dates of death.

The Current Beneficiary Survey, a new project in the pilot test stage, would, if approved as an ongoing survey, regularly collect detailed information about a limited sample of beneficiaries. In some instances, researchers could use the data from this survey, linked to the National Claims History and the UCDS, to investigate the effects of different treatments on health and functional status (i.e., ability to walk).

Through these combined efforts, epidemiologists and effectiveness researchers will have access to data of an unprecedented breadth, depth, variety and clinical detail. They will not need to enroll patients in clinical trials of existing but unproven treatments, but will be able to conduct sophisticated investigations, through data, into the impact of medical care as it is actually practiced.

To take one example, HCFA researchers have already used linked HCFA databases to investigate whether bypass surgery, angioplasty or medical treatment best improve a heart attack victim's prospects for survival, depending upon that patient's severity of illness. The data enhancements will better enable us to make answer questions about those three treatments' effect on survivors' health and functional status -- i.e., are they able to take long walks a year after the attacks?

Effectiveness Research

HCFA's Office of Research and Demonstrations has over 20 projects ongoing in the area of effectiveness, outcomes, and quality of care. For example, we are linking our data to registries maintained by the National Cancer Institute, to determine the patterns of care, co-morbidities and outcomes of different types and stages of cancer.

In addition, we have funded several different projects to develop outcome and other measures to assess the quality of home health agency services.

Other HCFA investigations are examining patterns of health outcomes. We have begun analyzing mortality rates, readmission rates, duration of hospitalization, and hospital expenditure data for 38 conditions and procedures, by geographic area. We will provide the PROs with this information.

Educational Efforts

PROs have been pilot-testing a method for carrying on our dialogue with the medical community: the small area variations approach pioneered in Maine by Dr. John Wennberg. Dr. Wennberg convened small study groups of physicians and provided them with information on variations in the rates of medical procedures among local communities. Wennberg found that after physicians had the opportunity in the study groups to compare their rates and discuss their philosophies of care, the rates of the procedures studied decreased substantially and the variations between communities diminished.

We found the study groups stimulated physician interest in knowledge about the outcome and effectiveness of medical care and in continuing this feedback process. In the future, we expect PROs to use this approach to disseminate new practice guidelines and research findings, and to draw local physicians' attention to concerns about local patterns of outcomes or care.

The HCFA-AHCPR Relationship.

HCFA and AHCPR cooperate on a number of fronts. First, we have a formal arrangement under which HCFA develops and supplies data needed by AHCPR's patient outcomes research teams (PORTs). Our experts also aid the research teams in using the data. These data are expected to yield valuable results.

Our two agencies also work together on outcomes research. We are jointly sponsoring the Medicare Post-Hospital Outcomes Study, which will track Medicare patients following their discharge from the hospital for certain medical and surgical conditions. The study will compare a patient's symptoms and functional status before hospitalization to his or her status at different intervals after discharge.

We are also collaborating on the design of a potential Medicare Beneficiary Health Status Registry, which -- if implemented -- would provide, in essence, medical histories for a large sample of beneficiaries entering the Medicare program. We are currently studying the feasibility of collecting this information at a reasonable cost.

Registry data would provide researchers with key information on health status and risk factors unavailable from any other source and, most importantly, would provide that information for vulnerable subgroups of beneficiaries. For the first time, we would be able to measure the relationship between health status, health behavior, and the use of health care services. In a data-based study of lung cancer, asthma or heart disease, for example, the survey would provide a key piece of information: whether a beneficiary had been a smoker years ago.

HCFA's PROs will participate in a study to develop and evaluate review criteria based on AHCPR's practice guidelines, and will disseminate the guidelines. The study will begin with the guidelines on benign prostatic hypertrophy, urinary incontinence and post-surgical pain, which are now undergoing peer review. HCFA and AHCPR staff are now working together to design the project.

HCFA Coverage Decisions

While we plan to use AHCPR's practice guidelines in a number of ways, we do not expect to make wholesale changes in our coverage policies when we receive them, or even after they have been tried and tested. It is important that the medical community fully understand practice guidelines, and adopts them voluntarily.

I would note, however, that HCFA requests and receives recommendations on major coverage decisions from the Office of Health Technology Assessment (OHTA), which is now a part of AHCPR. OHTA's assessment would naturally be informed by the findings of the patient outcome research teams and the guidelines developed by the Forum for Quality and Effectiveness in Health Care.

Conclusion

Effectiveness research and practice guidelines have the potential to substantially improve the quality of health care in this country and the value we get for our health care dollar. They also could provide a more appropriate standard of care for use in medical liability cases. We should not, however, expect that they will work miracles in restraining the rising spiral of U.S. health care costs.

Guidelines may indeed affect the cost of health care, but whether they will increase or decrease those expenditures is unclear. One hypothetical guideline might indeed save us money, by recommending that a large fraction of patients for whom cardiac bypass surgery has been proposed would be more appropriately treated through medical intervention. However, another guideline might indicate that some expensive service or procedure is underutilized, so that providing more appropriate care would increase health care spending.

As you can see, the cost impact of practice guidelines may not be in one direction only. But the impact on quality care is obvious: We should get better value for the dollars we do spend.

I emphasize that our dialogue with the health care community on what works in medical care will be a continuing process. When we provide practitioners with the scientific evidence available about the choices for treating a given condition, we will be eagerly listening for their feedback on the results of using these guidelines. The guidelines will be revised to incorporate the new information, and the process will begin again.

Ideally, the quality of patient care will improve with each exchange. But medical practice will not be transformed overnight. It is important that we retain the support of the many different groups of health care professionals, institutional providers and consumer advocacy organizations now committed to the pursuit of effectiveness in medical care.

I look forward to continuing to work with the Congress, with AHCPR and others in the Department, and with the health care and patient communities to bring about this transformation of medical practice.

Thank you. I will be happy to answer any questions you may have.

Chairman STARK. Thank you.
Dr. Clinton.

STATEMENT OF J. JARRETT CLINTON M.D., ADMINISTRATOR, AGENCY FOR HEALTH CARE POLICY AND RESEARCH, U.S. PUBLIC HEALTH SERVICE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. CLINTON. Mr. Chairman, I am pleased to be here this morning to discuss the medical effectiveness and outcomes activity of the Department and the Agency for Health Care Policy and Research.

I would like to begin by acknowledging the instrumental role of this subcommittee in developing the important new programs being undertaken by AHCPR. All of our medical effectiveness activities—which we refer to as the Medical Treatment and Effectiveness Program, the acronym MEDTEP—owe much to the initiative of this subcommittee.

The four-part Department-wide MEDTEP strategy combines an emphasis on outcomes and effectiveness research; the refinement and further development of relevant data systems; development of clinical practice guidelines; and dissemination and assimilation of new information about what works and does not work in health care. Further, the components of the effectiveness and outcomes program reinforce and complement each other. These interactions are outlined in a diagram appended to the more extensive statement for the record, which brings you up to date on the major AHCPR effectiveness and outcomes activities. Today let me highlight some of the findings from our work to date, our current plans, and our future activities.

This subcommittee has been particularly, and appropriately, concerned with the many problems we face with regard to data and information about health care delivery and financing.

Information is everywhere—in hospitals, in physicians' offices, centers providing many different kinds of ambulatory care, professional associations, and a myriad of other entities and groups. But most of these data do not help us answer crucial questions about how to better organize, pay for, and treat, in regard to medical care.

AHCPR hopes to help create integrated data systems that can provide better information on the cost effectiveness and value of our investments in health care. Our recent report to Congress on the feasibility of linking databases addresses our plans in this area. We will actively address these impediments, most immediately by pursuing several areas.

First, we are targeting patient care data for medical effectiveness research. We will work with and enhance existing payer sources, such as the Medicare claims files and the UCDS mentioned by Dr. Wilensky and collections from private health insurers, as well as improving existing State health databases.

Further, we are focusing attention to overcoming barriers to an automated medical record development, and we recently sponsored an Institute of Medicine workshop on this subject.

Our outcomes and medical effectiveness research includes major long-term patient outcome research team—these are referred to as PORT—projects, and smaller projects on more limited studies of effectiveness.

As of September 1990, 11 PORT projects, listed in the attachment to my longer statement, were funded. Each of these projects represents a substantial commitment. Valuable interim findings have already been produced.

For example, the literature review on low back pain suggests that the early use of diagnostic imaging procedures, such as x rays, yields limited information and is costly.

Second, wide variations in the rates of use of cardiac catherization—9 percent in the Northeast compared to 29 percent in the Southeast and the Great Plains—demonstrates a lack of general consensus about when it should be used. In contrast, somewhat greater consensus exists regarding coronary artery bypass surgery.

And preliminary literature review finds no evidence to support the use of four eye tests commonly used to assess patients for cataract surgery.

We take advantage of these interim findings and the expertise assembled in the PORT team to better inform and facilitate the guideline development work. For example, the cataract and the benign prostatic hyperplasia, or prostate disease, PORTS have provided extensive assistance to the guideline panels in literature review activities.

Perhaps the most difficult job you gave us is in the development, the refinement, dissemination, and evaluation of clinical practice guidelines. Guidelines have long been a part of health professionals' practices, but there are many guidelines developed by numerous organizations. They are profession specific, disease or procedure specific, hospital or practice-setting specific, and their quality varies considerably.

The Congress asked us to facilitate guidelines that would be broader and adaptable to national use for a variety of professionals, patients, and payers.

With the assistance of the Institute of Medicine, we have defined guidelines as professionally-derived statements intended to fully inform providers and consumers about the appropriate prevention, diagnosis, and treatment of specific health conditions.

Since this is a new undertaking, but one that we must accomplish quickly, we sought extensive public and private involvement and discussion.

For the first year, we chose to pursue what was to us the most efficient and effective format for guidelines development—the convening of multidisciplinary panels of experts and health care consumers. We named seven panels in 1990 to develop practice guidelines for the following conditions and procedures: Diagnosis and treatment of prostate disease—benign prostatic hyperplasia; treatment of cataracts in the aging eye; treatment of urinary incontinence in adults; prediction, prevention, and early treatment of pressure sores—decubiti, or bedsores they are sometimes referred to—in adults; management of acute postoperative pain; diagnosis and treatment of depressed outpatients in the primary care setting; and delivery of comprehensive care in sickle-cell disease.

All of these panels are in various stages of development. Some of them are near the end of their work and others are well underway. Draft guidelines for three conditions—the diagnosis and treatment of benign prostatic hyperplasia, or prostate disease; the management of acute postoperative pain; and urinary incontinence in adults—were developed by January 1991, as you specified in OBRA 1989. They are now undergoing peer review and limited pilot testing. We expect them to be available for dissemination in the early fall, and we are working with HCFA, the PRO's, and other groups to facilitate the full dissemination and assimilation of the guidelines information.

To further explore the other promising formats for guideline development, we will arrange for three guidelines by contract this fiscal year. We also will organize additional panels, and we continue to be open to suggestions for alternative approaches to guideline development. I want to highlight that guidelines will be based on what we know today, and the research underway will contribute to the necessary revisions and updates over time of AHCPR-assisted guidelines.

I would like to emphasize a common theme across the guidelines, and that is the importance of involving patients in the clinical decisionmaking process. For example, men with symptoms of benign prostatic hyperplasia—prostate disease—must be informed that they have more treatment options than surgery and that there are benefits and risks which they should weigh carefully with each option. Early detection and assistance in the management of urinary incontinence can preclude the necessity of accepting incontinence as an inevitable attribute of aging, and perhaps avoid unnecessary long-term care.

The final step in the MEDTEP process is the dissemination of the information we generate and assuring that it is assimilated into medical practice. This is challenging but pivotal to changing American medical care practice patterns.

For each guideline we will have a targeted plan for disseminating and facilitating the assimilation of new information. No one knows clearly how to change physician practice patterns or consumer behavior and expectations. But we will be innovative and bold as we pursue this diffusion of new information.

Further, we have established a new grant program to encourage research on the effectiveness of dissemination, that will guide the translation of research findings and guidelines into medical practice.

Mr. Chairman, the Secretary of Health and Human Services, those of us in the Public Health Service, and Dr. Wilensky and her staff at HCFA are committed to the importance of these effectiveness and outcomes activities and to the need to rapidly demonstrate progress in our research, our data development, and our guideline efforts.

As I indicated earlier, the information generated in our research needs to be fed back into practice guidelines, data development, and dissemination activities. Similarly, data development can advance research and guideline development. These processes are interacting and reciprocal.

Only then will the effectiveness and outcomes program have the desired effect of rationalizing medical practice in this country by helping physicians and patients better understand both the limitations and the possibilities of medical care—and knowing with more certainty what works and what does not. I believe we have made a sound beginning to a comprehensive program to accomplish these endeavors.

Thank you for this opportunity this morning. I will be pleased to answer your questions.

[The prepared statement follows:]

Statement

of

J. JARRETT CLINTON, M.D.

ADMINISTRATOR

Agency for Health Care Policy and Research
U.S. Public Health Service
Department of Health and Human Services

I'm happy to be here this morning, Mr. Chairman, to discuss the medical effectiveness and outcomes activities of the Department and the Agency for Health Care Policy and Research (AHCPR).

I'd like to begin by acknowledging the instrumental role of this subcommittee in developing the important new programs being undertaken by AHCPR. All of our medical effectiveness activities -- which we refer to as the Medical Treatment and Effectiveness Program (MEDTEP) -- owe much to the initiative of this subcommittee and its members.

The four-part MEDTEP strategy combines an emphasis on outcomes and effectiveness research; the refinement and further development of relevant data systems; development of clinical practice guidelines; and, dissemination of new information about what works and does not work in health care. Further, the components of the effectiveness and outcomes program reinforce and compliment each other.

I have attached a statement that brings you up to date on the major AHCPR effectiveness and outcomes activities. Today, let me just highlight some findings from our work to date, our current plans, and our future activities.

Data Development

This subcommittee has been particularly -- and rightly -- concerned for some time with the many problems we as a nation face with regard to data and information about health care delivery and financing.

Information is everywhere -- in hospitals, physicians offices, centers providing many different kinds of ambulatory care, professional associations, and a myriad of other entities and groups. But most of these data do not help us answer crucial questions about how to better organize and pay for medical care.

AHCPR hopes to help create integrated data systems that can provide better information on the cost-effectiveness and value of our investments in health care. Our recent Report to Congress on the feasibility of linking data bases addresses our plans in this area. We will actively address these impediments, most immediately by pursuing several areas.

First, we are targeting patient care data for medical effectiveness research. We will try to work with and enhance existing data payer sources, such as the Medicare Claims files, the Medicare UCDS, and collections from private health insurers, as well as improving existing State data bases.

More specifically, we are focusing attention on overcoming barriers to automated patient record development, and recently sponsored an Institute of Medicine (IOM) workshop on this subject.

Outcomes Research

Our outcomes and medical effectiveness research includes major, long-term Patient Outcome Research Teams (PORT) projects and smaller projects on more limited areas of effectiveness.

As of September 1990, 11 PORT projects, listed in the attachment to my longer statement, were funded. Each of these 5-year projects represents a substantial, long-term commitment. Valuable interim findings have already been produced.

A great deal of significant information is being generated by PORTs and other MEDTEP research. A few examples include:

- Literature review on low back pain suggests that widely used diagnostic imaging procedures, such as x-rays, yield limited information, are costly, and occasionally are harmful;

- Wide variations in rates of use of cardiac catheterization (9% in the Northeast to 29% in the Southeast and Great Plains) demonstrates a lack of general consensus about when it should be used. In contrast, somewhat greater consensus exists regarding bypass surgery;

- Computer-displayed messages can effectively decrease physician use of diagnostic tests, which account for a significant portion of total health care expenditures.

We've told the PORT investigators to emphasize dissemination of these interim findings, and they have been creative in doing this. The low back pain PORT, for example, produces a newsletter.

We take advantage of interim findings and the expertise assembled in a PORT team to better inform and facilitate the guideline development work. For example, the cataract and benign prostatic hyperplasia (BPH) PORTs have provided extensive assistance to guideline panels in literature review activities.

Guidelines

Perhaps the most difficult job you gave us in OBRA 1989 is the development, refinement, dissemination and evaluation of clinical practice guidelines. Guidelines have long been a part of health professionals' practices, but there are many guidelines developed by numerous organizations. They are profession-specific, disease or procedure specific, hospital or practice-setting specific -- and their quality varies considerably.

The Congress asked us to develop guidelines that would be broader, and adaptable to national use by a variety of professionals, patients, and payers.

We have defined guidelines as professionally derived statements intended to inform providers and consumers about the appropriate prevention, diagnosis, and treatment of specific health conditions.

Since this is a new undertaking -- but one that we must accomplish quickly -- we sought extensive public and private involvement.

For the first year, we chose to pursue what was to us the most efficient and effective format for guideline development -- the convening of multidisciplinary panels of experts and health care consumers. We named seven panels this year, to develop practice guidelines for these conditions and procedures:

- Diagnosis and treatment of benign prostatic hyperplasia;

- Treatment of visual impairment due to cataracts in the aging eye;

- Treatment of urinary incontinence in adults;

- Prediction, prevention, and early treatment of pressure sores in adults;

- Management of acute postoperative pain;

- Diagnosis and treatment of depressed outpatients in primary care settings; and,

- Delivery of comprehensive care in sickle cell disease.

All of these panels are in various stages of development. Some of these panels are near the end of their work and are well

underway. However, draft guidelines for three conditions -- diagnosis and treatment of benign prostatic hyperplasia, management of acute postoperative pain, and urinary incontinence in adults -- were developed by January 1991, as you specified in OBRA 1989. They are currently undergoing peer review and limited pilot testing. We expect them to be available for dissemination in the early fall, and we are working with HCFA to coordinate these efforts with the Peer Review Organizations.

To explore another promising format for guideline development, we will arrange for three guidelines by contract later this year. We will also organize additional panels, and we continue to be open to suggestions for other alternative approaches to guideline development.

Dissemination and Assimilation

The final step in the MEDTEP process is disseminating the information we generate, and assuring that it is assimilated into medical practice. This is difficult, but it is pivotal to changing the scene in American medicine.

A common theme across the draft guidelines and the panels is the importance of involving patients in the clinical decision-making process.

For example, men with symptoms of benign prostatic hyperplasia must be informed that they have more treatment options than surgery and that there are benefits and risks with each option they must weigh.

Early detection and assistance in management of urinary incontinence can preclude the necessity of accepting incontinence as an inevitable attribute of aging, -- and perhaps can avoid unnecessary long term care.

We will have a targeted plan for disseminating each guideline.

We are concerned that no one knows clearly how to change physician behavior and practice patterns, or consumer behavior and expectations. We will be innovative and bold as we pursue this issue.

Further, we have established a new grant program to encourage research on the effectiveness of dissemination that will study the most productive ways to translate research findings and guidelines into medical practice.

Conclusion

Mr. Chairman, the Secretary, those of us in the Public Health Service, and Dr. Wilensky and her staff at HCFA are committed to the importance of these effectiveness and outcomes activities and to the need to rapidly realize progress in our research, data development, and guideline efforts.

As I indicated earlier, the information generated in our research needs to be fed back into practice guidelines, data development, and dissemination activities. Similarly, data development can advance research and guideline development. The processes must be interacting and reciprocal.

Only then will the effectiveness and outcomes program have the desired effect of rationalizing medical practice in this country by helping physicians and patients better understand both the limitations and the possibilities of medical care -- and knowing with more certainty what works and what does not work. I believe [illegible] sound [illegible] comprehe[illegible] accomplish these endeavors.

Thank you for giving me this opportunity to testify this morning. I would be pleased to answer questions from the subcommittee.

Statement for the Record

Administrator
Agency for Health Care Policy and Research

before the

Health Subcommittee
Ways and Means Committee
House of Representatives

April 30, 1991

Thank you, Mr. Chairman, for this opportunity to discuss the medical effectiveness activities of the Department and the Agency for Health Care Policy and Research (AHCPR).

Your subcommittee deliberations and Mr. Gradison's Medical Care Quality Research and Improvement Act of 1989 helped lay the groundwork for a new component of the Public Health Service, the Agency for Health Care Policy and Research. The purpose of AHCPR is to enhance the quality, appropriateness, and effectiveness of health care services through a broad program of scientific research and information dissemination. Since AHCPR was created in December 1989, I have had the opportunity and challenge of directing its work.

Today, I'll address AHCPR's medical effectiveness and outcomes activities. As you know, AHCPR and its predecessor reflect a long heritage of departmental commitment to scientific research and study of health care delivery and financing systems, including early research in geographic area variations during the 1970's and 1980's. We have built the medical effectiveness programs on that strong foundation as we identify, define, and disseminate information about what works, and what does not work in health care.

MEDTEP and Its Components

The Medical Treatment Effectiveness Program, which we call MEDTEP, has four interactive components designed to improve patient care through enhancing the scientific basis for clinical decisionmaking of health care providers and consumers. I'll describe our activities and programs in each of these four components -- data development, outcomes research, practice guideline development, and dissemination -- in some detail. I've displayed these basic concepts in the attached diagram, which shows their interrelationships.

Data Development

We need to increase the quantity and quality of administrative and clinical data available for health services research, with special emphasis on patient outcomes research. This is primarily accomplished by identifying and evaluating the usefulness of existing data bases to support research on patient outcomes.

AHCPR's Office of Science and Data Development (OSDD) is primarily concerned with the establishment of standards for uniform methods of developing and collecting data and with investigating the feasibility of linking research-related data with data collected or maintained by both Federal and non-Federal entities and by agencies within DHHS.

Another priority is developing uniform definitions of data, common reporting formats and linkages, and ensuring the security, confidentiality, accuracy, and appropriate maintenance of data as specified in the law.

Our collaboration with HCFA on these data issues is critical. Our joint effort focuses on timely transfer of special HCFA data tapes to MEDTEP researchers. We are also working with HCFA to

develop a longitudinal survey of the functional status of a sample of Medicare beneficiaries, and a functional status measure of Medicare beneficiaries some months after hospitalization. This new arrangement between PHS and HCFA has developed rapidly and with a superb spirit of collaboration.

In fiscal year 1990, AHCPR obligated $6.1 million for data development. This includes $5.0 million transferred to HCFA to support several activities, including assistance in providing special data tapes to MEDTEP researchers.

Outcomes Research

AHCPR's Center for Medical Effectiveness Research (CMER) guides the research on patient outcomes and alternative strategies for the prevention, diagnosis, treatment, and management of clinical conditions. We conduct outcomes research through large-scale multidisciplinary studies called Patient Outcome Research Teams (PORTs), and through smaller grants, contracts, and intramural research.

PORTs build on earlier outcomes research by documenting, analyzing, and synthesizing scientific findings about the outcomes, effectiveness, and appropriateness of alternative medical strategies. PORTs are also concerned with the cost-effectiveness of clinical management strategies, and with the dissemination of their findings. Finally, PORTs review the impact of their dissemination efforts on improving treatment.

To be chosen for study a clinical condition must meet certain criteria:

- Large numbers of individuals are affected.
- There is uncertainty and/or controversy regarding effectiveness of treatment.
- The associated risks and/or costs of treatment are high.
- The needs of Medicare beneficiaries are addressed.
- Data are available or can be readily developed.

As of September 30, 1990, 11 PORT projects, listed in the attachment, were funded. Each of these 5-year projects represents a substantial, long-term commitment, but valuable interim products have already been produced.

We've told the PORT investigators to emphasize dissemination of interim findings, and they have been creative in doing this. The low back pain PORT, for example, produces a newsletter. A recent issue contained brief information about a Washington State study to review surgery rates between counties, testing 28 possible variables for explaining the differences. The newsletter reports that the rate of surgery for low back pain varied nearly fifteenfold among counties, with the explanatory variables accounting for only a minor part of the variability.

Obviously, the critical information about why the variations exist and how to identify the most appropriate surgery rate remain on this PORT's agenda. But my point is that all of the PORTS are working constantly to refine our knowledge in their area of expertise, and are not waiting until the end of a very long project to produce interim information and results.

As I mentioned, our MEDTEP activities are interrelated, and we take advantage of interim findings and the expertise assembled in a PORT team to better inform and facilitate the guideline development work. For example, the cataract and benign prostatic

hyperplasia (BPH) PORTs have provided extensive assistance to guideline panels in literature review activities.

MEDTEP's many smaller projects focus on a particular facet of the broader objectives of PORTs. For example, they will synthesize literature on medical effectiveness, address methodological issues such as how to measure essential patient outcomes of care, or study problems related to clinical guideline use or assimilation. A few of the many topic areas currently under study are management of diarrhea, stroke prevention, and congestive heart failure.

A great deal of significant information is being generated by PORTs and other MEDTEP research. A few examples include:

- Literature review on low back pain suggests that widely used diagnostic imaging procedures yield limited information, are costly, and occasionally are harmful;

- Wide variations in rates of use of cardiac catheterization (9% in the Northeast to 29% in the Southeast and Great Plains) demonstrates a lack of general consensus about when it should be used. In contrast, somewhat greater consensus exists regarding bypass surgery;

- Computer-displayed messages can effectively decrease physician use of diagnostic tests, which account for a significant portion of total health care expenditures.

Practice Guideline Development

A critical new responsibility assigned to AHCPR is the development, review, and updating of clinical practice guidelines. This activity is facilitated by AHCPR's Forum for Quality and Effectiveness in Health Care.

We have sought extensive public and private involvement in this first year of guideline development. We invited over 500 organizations to participate in the process. We held scores of meetings to elicit assistance from special groups. And we convened workshops with leaders from nursing, allied health professions, and State and local government.

For our initial effort in guideline development, we chose to convene multidisciplinary panels of experts and health care consumers. In our first year, guideline panels were established for seven conditions and procedures:

- Diagnosis and treatment of benign prostatic hyperplasia;

- Treatment of visual impairment due to cataracts in the aging eye;

- Treatment of urinary incontinence in adults;

- Prediction, prevention, and early treatment of pressure sores in adults;

- Management of acute postoperative pain;

- Diagnosis and treatment of depressed outpatients in primary care settings; and,

- Delivery of comprehensive care in sickle cell disease.

We sought panel members who are broadly representative of health care providers involved in treating a given medical condition. Each panel includes primary and specialty physicians, nurses, selected allied health disciplines as appropriate, and consumers.

We sought and received extensive help from IOM in defining the process.

Although the initial seven guideline panels are in various stages of development, with some nearing the end and others still shaping their work, draft guidelines for management of three clinical conditions were developed by January 1991. The three initial guidelines -- diagnosis and treatment of benign prostatic hyperplasia, management of acute postoperative pain, and urinary incontinence in adults -- are undergoing peer review and limited pilot testing now. We expect them to be widely available in the early fall.

The guidelines development process, too, produces useful information as we go along. For example, we chose the subject of urinary incontinence in adults for guideline development after nursing professionals pointed out to us the enormous impact of this disease on nursing home admissions.

Similarly, the panel working on BPH has found in talking to patients that they are not always as interested in surgery as physicians would think.

These first efforts taught us that production of a practice guideline is more complex and time consuming than we and the expert panels anticipated. This is due largely to the huge amount of scientific information to be systematically reviewed and analyzed.

A common theme across the draft guidelines and the panels is the importance of involving patients in the clinical decision-making process. For example, men with symptoms of benign prostatic hyperplasia must be informed that they have more treatment options than surgery and that there are benefits and risks with each option that must be weighed. Early detection and assistance in management of urinary incontinence can preclude the necessity of accepting incontinence as an inevitable attribute of aging or a post surgical complication, and perhaps avoid unnecessary long term care. And, post surgery patients are most adequately managed for pain if the options available for pain management have been reviewed with them early in the course of treatment.

Use and dissemination of the guidelines, and their evaluation, are the next important steps in this endeavor. Our collaboration with HCFA is critical to these activities. We are working to assure that the guidelines are compatible with HCFA's Uniform Clinical Data System (UCDS) formats. Evaluation, review, and refinement of the guidelines will be a continuing process and ongoing cooperation and collaboration with HCFA is required to produce useful, effective, and practical guidelines.

Many more guideline activities are underway. We have announced new guideline panels for HIV/AIDs and low back pain that begin later this year. To explore another promising approach to guideline development, we plan to arrange for three guidelines by contract. Additional panels will begin work on the quality aspects of mammography on early detection of breast cancer and management of cerebral vascular accident (strokes). We expect to spend approximately $7 million in fiscal years 1990 and 1991 to facilitate development of practice guidelines.

Dissemination and Assimilation

MEDTEP guidelines and information must be disseminated to a variety of individuals and groups, and then assimilated into medical practice. AHCPR's Center for Research Dissemination and Liaison (CRDL) works with other staff to coordinate an array of dissemination activities, ranging from evaluation of the most effective [illegible]

providers to change their practice patterns, to strategies for reaching particular audiences.

We will have multiple, specific dissemination plans for each clinical practice guideline. Our strategy will emphasize assuring adoption and use of the guideline. We will use many methods of information dissemination, including print, direct mail, computer search systems, video tapes, press, exhibits, and presentations.

We are also using resources and expertise of the National Institutes of Health's National Library of Medicine (NLM) to assist in literature review, cataloging, and disseminating clinical practice guidelines.

Further, we have engaged the Health Resources and Services Administration (HRSA) for dissemination to selected health professions education networks such as the Geriatric Education Centers and Area Health Education Centers. We have also developed strong communication links with professional organizations, specialty societies, and State and local medical societies.

We are consulting dissemination experts, and will discuss the adoption of research findings and guidelines into medical practice at national workshops and conferences. Finally, we have established a grant program for research in dissemination effectiveness. This program will study one of the nation's most difficult problems -- how to effectively assimilate research and guidelines into everyday medical practice. Its initial focus will be to examine the process and structural factors underlying the diffusion and adoption of scientific information.

For fiscal year 1990, we obligated $2.5 million to strengthen and expand these dissemination and liaison activities.

Conclusion

In conclusion, Mr. Chairman, I would like to stress again the Secretary's strong commitment to research, data and guideline development, and dissemination on medical effectiveness, and the intradepartmental nature of our work.

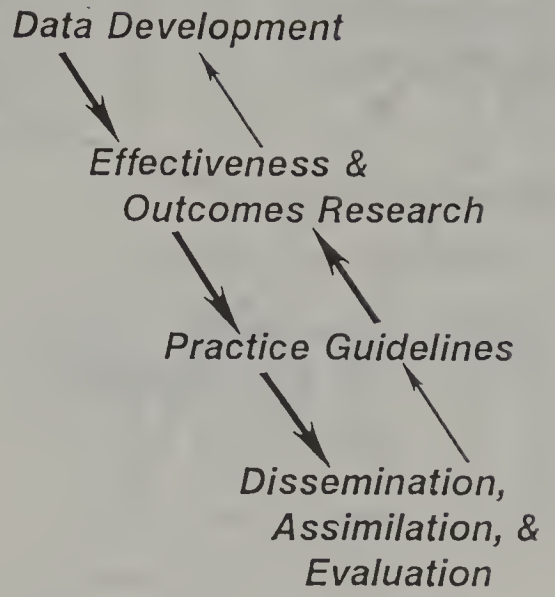
As I indicated earlier, the information generated in our research needs to be fed back into practice guidelines, data development and dissemination activities. Only then will the MEDTEP initiative have the desired effect of rationalizing medical practice in this country, helping physicians and patients better understand both the limitations and the possibilities of medical care--and knowing with more certainty what works and what does not work in health care.

We also continue to seek advice and assistance from a large group of outside organizations and individuals. And, as I noted, we are learning a great deal as we progress. We intend to keep an open mind and listen to new ideas and suggestions.

For example, we have become particularly aware of the need for patient involvement in clinical decision-making processes, and will be stressing this need for consumer involvement in future work. We look forward to hearing from other witnesses today about their ideas for improving our processes.

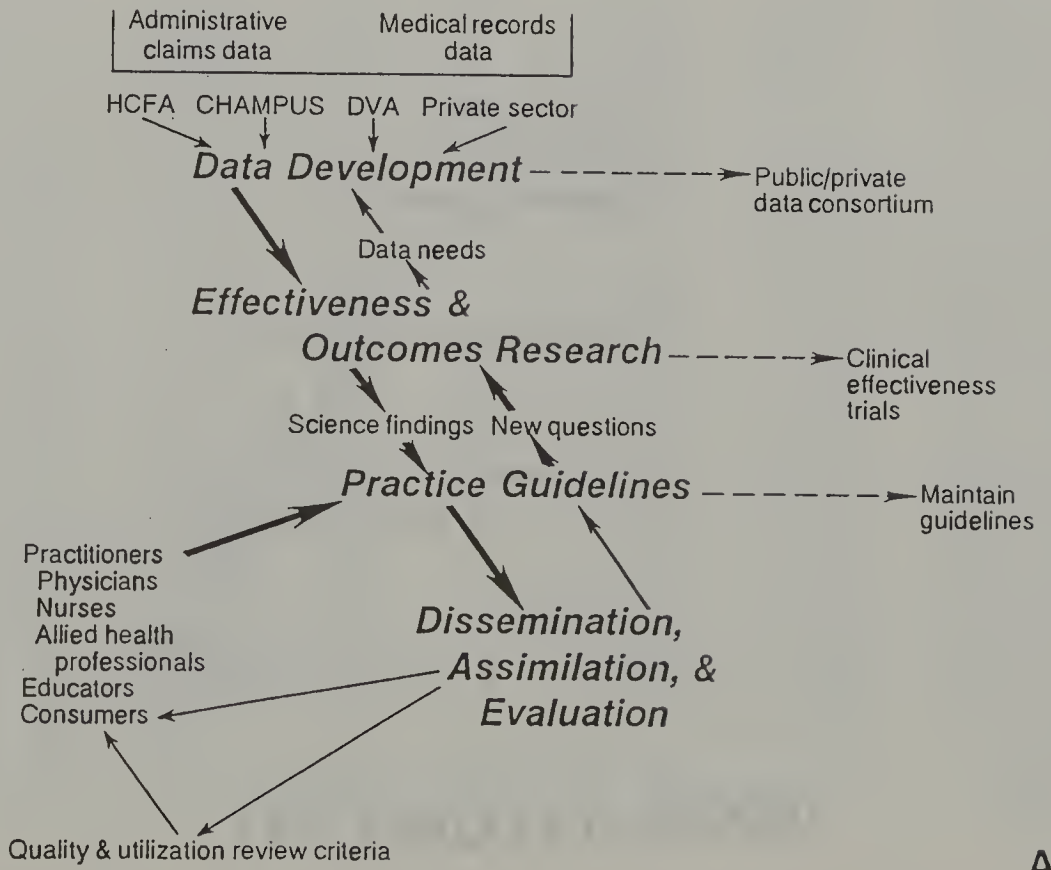
Thank you for giving me this opportunity to testify this morning. I would be pleased to answer questions the subcommittee may have.

The MEDTEP Model



AHCPR

The MEDTEP Model



AHCPR

MEDTEP Research
Patient Outcomes Research Teams (PORTs)

Project Title	Principal Investigator	Project Period
"Back Pain Outcome Assessment Team"	Richard A. Deyo, M.D. University of Washington Seattle, WA	9/89-8/94
"Assessing and Improving Outcomes: Total Knee Replacements"	Deborah A. Freund, Ph.D., M.P.H. Indiana University Indianapolis, IN	4/90-3/94
"The Consequences of Variation in Treatment for Acute Myocardial Infarction"	Barbara J. McNeil, M.D., Ph.D. Harvard Medical School Boston, MA	9/89-8/94
"Variations in Cataract Management: Patient and Economic Outcomes"	Earl P. Steinberg, M.D. Johns Hopkins University Baltimore, MD	9/89-8/94
"Assessing Therapies for Benign Prostatic Hypertrophy and Localized Prostate Cancer"	John E. Wennberg, M.D., M.P.H. Dartmouth Medical School Hanover, NH	9/89-8/94
"Outcome Assessment Program in Ischemic Heart Disease"	David B. Pryor, M.D. Duke University Medical Center Durham, NC	7/90-6/95
"Outcome Assessment of Patients with Biliary Tract Disease"	J. Sanford Schwartz, M.D. University of Pennsylvania Philadelphia, PA	8/90-7/95
"Analysis of Practices: Hip Fracture Repair and Osteoarthritis	James I. Hudson, M.D. University of Maryland College Park, MD	9/90-9/95
"Variations in the Management and Outcomes of Diabetes"	Sheldon Greenfield, M.D. New England Medical Center Boston, MA	9/90-9/95
"Assessment of the Variation and Outcomes of Pneumonia"	Wishwa N. Kapoor, M.D. University of Pittsburgh Pittsburgh, PA	9/90-9/95
"Variation in Obstetric Practice and Patient Outcomes"	Emmett Keeler, Ph.D. The RAND Corp. Santa Monica, CA	9/90-9/95

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Chairman STARK. Thank you.

You both have stressed the importance of this program, and yet we are going to spend $63 million in 1992. Shouldn't we spend more? Gail?

Ms. WILENSKY. Well, the number that you cited is directly related to the MEDTEP program and AHCPR. As I have indicated, we are spending more money, at least several millions of dollars within HCFA, because of the work that we are doing as part of our uniform clinical data set.

Chairman STARK. We are going to hear from Rand, and they would like us to spend another $10 or $15 million here. You know, $10, $15 million adds up here and there. But when we are talking about $120 billion or, indeed, $600 billion nationwide, sometimes, money won't move anything. Expenditure may be marginal. But to the extent that the research community says we could be moving on it a little more quickly, let's assume that we will find the money for you in a way we could agree on.

Doctor, what do you think? Should we spend some more? If everybody wants to testify today that we are spending plenty of money, I don't intend to just try and raise it to say that. But I think everybody today is going to agree there are some real benefits in this. It seems a paltry sum.

Ms. WILENSKY. Let me just add this, and then I will turn it over to Jarrett.

The problem we have now is not so much that we are lacking guidelines. I think the number I saw was some 1,100 guidelines of various sorts that specialty societies and other groups have put together. The difficulty, as I have been hearing from some of the Rand people, is that in order to have these guidelines be effective, there really needs to be at least two parts to them that are harder to come by. One is that they really need to be based on good research, and the second is they need to be very detailed.

What that means is—I don't know whether we could use a little more money effectively, and the answer is we probably could use some more money effectively. I am not sure whether large amounts would resolve this particular problem in terms of really getting the information on outcomes and effectiveness. But we always end up spending relatively small amounts for our information relative to the huge amounts we spend on actually carrying out programs, and there is just no denying that.

Chairman STARK. You don't feel that we are spending too much and that this is an area you have to hold down expenditures?

Ms. WILENSKY. Oh, no, I don't. I don't think we are spending too much.

Chairman STARK. OK. One other issue. There are already a variety of practice guidelines that have been developed as a result of the research that has been going on and is going on right now. Could we use them now? Would you support a demonstration project to, say, take some guidelines that we already have and have a pilot project or demonstration and sort of see if we can plug them into the system?

Ms. WILENSKY. We are planning on starting one in September. The answer is yes, it is what we are planning jointly, our two agencies, starting in September, and it is very much what this uniform

clinical data set, that we have been working on the last 3 years, is all about.

Chairman STARK. What kinds of things? Can you tell us?

Ms. WILENSKY. This is a 2-year study that we are planning to start in September.

Chairman STARK. I mean using which guidelines.

Ms. WILENSKY. I think the three.

Dr. CLINTON. We have three that have been identified as ready to move with. One of this is benign prostatic hyperplasia.

Chairman STARK. I am not sure I know what that is, and I am not sure I want to.

Dr. CLINTON. Prostate disease. Benign—noncancerous—prostate disease. This is work that would be almost entirely in the Medicare population, and it is logical that we use the PRO's both to develop the quality measurement devices, the dissemination process, and engage that whole system. We will use other groups to look at two of the other guidelines that will be ready by fall.

Chairman STARK. OK. Now, does that mean that we will turn away, in effect, from utilization review? It seems to me we are saving $10 for every $1 we spend. And this is not going to replace utilization?

Ms. WILENSKY. No, no. What it is really doing is refining utilization review, and it relates more to the PRO Program, although part of what we are doing is to make sure that we are integrating the medical audit activities of the carriers, our contractors, with the PRO's. And we have, in fact, been making sure that when we are moving forward in this area of changing our PRO system to outcomes and patterns of care, that we are doing so in ways that are consistent with the medical audits that are going on by the carriers.

But this initially will help us in the PRO review of work that goes on in the hospital and in identifying patterns of care that appear to be working and those that do not appear to have good outcomes associated with them, so that PRO's can feed that information back to physicians, so that they can change their patterns of care. PRO's will have a more systematic way to look for problems than doing case-by-case review after the fact that they have, to date, used.

Chairman STARK. With my limited understanding of the prostate procedures, it seems to me that you are never going to know that they work or don't work, but that in x percentage of the time it helps or it prevents cancer. It still is going to be, whatever you come up with, a decision that I—as a patient—would make, or my physician would attempt to persuade me or dissuade me, depending upon his or her advice.

This doesn't lead to absolutes, I gather. In other words, this will make it somewhat easier for me to understand my chances, the physician to better understand what the chances are for someone with my symptoms or my lack of symptoms, because the decision will be based on more empirical data than we have had. It won't force us to a decision. Is that it?

Dr. CLINTON. I think you have summarized it very well. It improves your decisionmaking as a patient. It clarifies the decisionmaking in which the physician participates. You have choices.

They have risks and benefits. You may be more adverse to surgery than your surgeon. You may be willing to take on greater risks than others who have the same symptoms and are quite willing to tolerate those, because they would like to avoid surgery.

So you have summarized it very well. The only thing I can clarify is that surgery for benign prostatic hyperplasia does not prevent cancer of the prostate. It is commonly misunderstood, and I will clarify that point. It is mainly to manage the symptoms.

Chairman STARK. You just exposed the fact—it's one that I stipulate to.

Dr. CLINTON. It's a common misunderstanding.

Ms. WILENSKY. I think the only case where it may do more than just providing useful guidance—I think that's the fundamental gain—is that it will provide both the physician and the patient with more information, given the patient's condition about the likely outcome, if they go in one direction or another.

Where practical guidelines could be more definitive—but they will not be, I think, used for this purpose until they are much clearer and accepted by the medical community—are in cases where there is no benefit.

Chairman STARK. Yes, what I'm saying is that you might determine that wearing a copper bracelet really doesn't help heart disease at all and you aren't going to pay for it.

Ms. WILENSKY. That's right.

Chairman STARK. I would presume that the medical fraternity would have to be almost unanimous in accepting that bit of news or that the physicians would be inclined, if even a small group of physicians wanted to keep trying something, my guess is that you'd let them. I don't know that, but——

Ms. WILENSKY. I think that ultimately, when the information was accepted that there were, in certain circumstances, procedures that have no value, then we would use the guidelines to delay payment. And at that point, it would do more than just providing more information.

Chairman STARK. OK.

Mr. Gradison.

Mr. GRADISON. Thank you, Mr. Chairman.

I would just like to, very briefly, explore a question of how this information might be made available to patients. The only specific instance that I've heard about was the tape which John Wennberg and others had developed for patients who were considering the options with regard to benign enlarged prostates.

I guess what really is in my mind is this question: Could you conceive of a situation where—with regard to certain potential surgical procedures—there would be a requirement that the patient have this information and have had an opportunity to review that information before they get to that point that they have to sign an informed-consent form before surgery?

Dr. CLINTON. Well, I think it does contribute to the whole question of fully informed consent. And the record ought to indicate that the options were provided whether it was on a video disc or whether it is provided in another format. It depends on how well developed that communication line is.

I think that's good for the patient, and I think it's good for the physician to protect and to document why that choice, among others, was taken in the event that someone returns to them and says, why did you do it this way?

Fully informed consent then, I think, is increasingly an important part, and I emphasize the word, fully, because we have always had some form of informed consent.

What we're finding in many of the nonlife-threatening diseases we're studying is that patients really do have strongly held values and beliefs about preferences for one kind of treatment versus another.

Mr. GRADISON. Thank you, very much.

Thank you, Mr. Chairman.

Chairman STARK. Mrs. Johnson.

Mrs. JOHNSON. Thank you, Mr. Chairman.

Current law does not hold physicians liable for civil penalties if they are acting in compliance with established guidelines. Have you discussed that in the context of this development of guidelines, particularly in the context of a demonstration project?

Dr. CLINTON. We have talked about that issue in a number of medical liability workshops, and conferences, and discussions in general. I think, generally, we believe, as do others in the medical profession, that scientifically based guidelines will protect physicians against liability charges. I think that we are very early in our guideline development process and would rather be assured that we're really on solid ground before we link them then to a liability protection device.

I would prefer to wait, I think, until we have the guideline development process a little bit further advanced before linking it.

Mrs. JOHNSON. I appreciate that we are at a very embryonic point. But it does interest me that the current PRO law has provisions which specifically provide immunity if a physician is following norms of practice. If they are not following norms of practice, they certainly are exposed to suit. I think that is something that as you develop the demonstration projects and protocols you should consider. Perhaps you might comment on this, Dr. Wilensky.

Ms. WILENSKY. You are correct that there is a provision in the Social Security Act that as long as the physician is following guidelines that have been adopted by the PRO, there is some protection, and that would still apply as long as they are following guidelines that have been provided by the PRO's.

I actually have long thought that one of the most important impacts outside the quality of care, in terms of cost, may well come from the use of the outcomes and guidelines work as providing a standard of care other than the standard that exists in the community, usually developed in a very unscientific method.

I think that this offers great promise for giving physicians a reason not to just do more and more activities. As the guidelines are adopted by PRO's, they could, indeed, provide that protection.

Mrs. JOHNSON. I think that's a very important point that they would be more soundly based in research than the sort of community standard of practice.

Ms. WILENSKY. Correct.

Mrs. JOHNSON. One other thing that you didn't address, and I think we're not prepared to address yet, but as we move forward on effectiveness research, are you beginning to think about the problem of evaluating technology from this point of view? One of the difficulties with that is that some of our technology has demonstrated its most important contribution well after it has been in play and in ways that weren't anticipated. But nonetheless, it does seem to me like there is a need in the system for better evaluation of technology earlier in its life cycle. I wonder if you have been thinking about that in planning your research activities?

Ms. WILENSKY. Well, you know, what we now do is rely on a part of the AHCPR, the Office of Health Care Technology Assessment, when we make an initial coverage decision. And as you are aware, we are becoming somewhat more sophisticated in terms of what some of those coverage decisions are. That is, we may do limited coverage rather than just full coverage, yes or no of a procedure.

I view the work that is being done in effectiveness as being an extension of the all-or-nothing type of coverage, or limited coverage and otherwise no coverage, that goes on. What is frequently the case is that a new technology will be very effective, but the question is properly identifying the circumstances where it really makes a difference. That is something that is different from the kind of advice we traditionally have received from the Office of Technology Assessment which is, is it now OK to bring in, under a certain set of circumstances, the use of a technology?

I think that the outcomes-effectiveness work will help us become much more discriminating in terms of the use; that is, that there are certain kinds of symptoms and circumstances where the technology may have a lot of gain. There may be a set of other circumstances, maybe the majority of potential uses, where new technology doesn't contribute anything more than is already available, maybe even something less.

So I see us as going from beyond the yes-no coverage to getting much more sophistication in the areas in which it really is more likely to make a difference, and to getting to be much more discriminating both as a consumer and as a purchaser.

Mrs. JOHNSON. Thank you.

Dr. CLINTON. I would only add that our technology assessment activities within AHCPR include not only equipment, the hardware, but also procedures—for example, a recent report on liver transplantations contributed to HCFA's determination about reimbursement coverage with regard to liver transplants.

Technology assessment then, and guideline development, interact a great deal. Certainly the gall bladder disease research that we're undertaking will be looking at the new laparoscopic procedures for doing the cholecystectomies. The guideline development group with regard to cataract has raised important technology assessment questions that deserve further attention than the literature would document at the present time.

So I believe you are quite correct that there is a great deal of interchange and we see both interactive work within our own agency, as well as continuing to contribute to the requirements of HCFA and CHAMPUS.

Mrs. JOHNSON. Thank you, very much. That was very interesting to me, thanks.

Chairman STARK. Mr. Levin.

Mr. LEVIN. Thank you, Mr. Chairman.

Hello to both of you. I will give a special hello to a long-time friend. I haven't seen you in quite a while, Jarrett. Nice to see you.

Dr. CLINTON. Good to see you.

Mr. LEVIN. The agency is as lucky there as they are with the head of HCFA. So let me ask you both, through the leadership of this subcommittee, our chairman, and surely Mr. Gradison, this area has been spot-lighted far beyond what it was several years ago.

I think that our constituents and the health community would like to glean some kind of a notion as to relative importance of outcome research. This year we're going to begin looking at the various pieces of health care delivery and try to undertake some changes.

There's the incessant argument about how bold we have to be and what steps are available. As I read both of your testimonies, it seemed to me that on one page you hold out substantial hope and then the next page there is caution, or maybe on the same page, there's both, and for good reason. But it's a little hard to discern where you put all of these efforts in the spectrum and what's driving it? How much of it relates to the quality? How much of it relates to issues of cost? How much can we expect if all of this works out well and it significantly helps us to control the escalating costs?

So within your approach of caution, where do you place this, more or less, in order of importance?

Ms. WILENSKY. Well, I would regard this as probably the most positive, appealing strategy that we can do, because it ought to provide us with the best shot at a win-win situation, particularly since, at the very least, this work will provide us with information about care that is just inappropriate, that has no positive value associated with it.

I don't think that's enormously large, but I also have read some of the information from Rand and some of the information that Dr. Chassin has prepared, and I think the level of inappropriate care might be as high, overall, as 8 to 10 percent. I mean, I don't know. I think that's always been about the ballpark figure that has been assumed.

I also think that there is a real potential with regard to the liability front. I think that's a big issue, not so much because of the malpractice suits—although that's obviously an issue—but because of the increasing amount of testing, and imaging, and other ancillary activities that can easily be justified out of concern for malpractice reasons. This kind of work could forestall that by providing a more sensible standard of care.

Early on, particularly, I think that we will be very reluctant to use information other than where we feel very comfortable that there's no appropriateness attached to it, no medical benefit. I do think that there will be some areas where we will find underuse. That issue was raised, that we will not only find out that we do too

much, but chances are we do too little of some things, and that will crop up.

Sometimes when you hear people talking about medical outcomes and effectiveness, they make noises like 30 percent of the care is either unnecessary or inappropriate and that we can just make massive changes of that order. I think that kind of magnitude is way off the mark, but I think that if we're talking about 5 to 10, maybe closer to 10 percent change, that's within the ballpark of feasibility. I don't know how you put that relative to other strategies.

The real appeal is that we would be doing something that would really help in terms of value and quality of health care, and not just making reductions in the somewhat arbitrary way that we're frequently forced to make. It's that combination that makes practice guidelines seem, even if the change is not huge in magnitude, so appealing.

Dr. CLINTON. I would only add that our contribution, I think, will improve the quality of care; it will improve the value for the dollar spent on that particular medical condition. But each time that we identify where there may be some cost-savings because something is unnecessary, there may be three other pieces of technology that have been brought into the marketplace that are very attractive, and people want to try those and use those. So that with each piece of medical information that we deal with, there may be the creation of three more. So we are chasing that to some extent.

I think that the patient outcomes research teams that have been established have already been responsive. As I indicated earlier, the gallbladder disease PORTS are already looking at laparoscopic cholecystectomy, a new way to take out the gallbladder that wasn't even talked about commonly 2 years ago.

So as things move fast we're going to be in a better position to make some assessments of the interventions, their risks, and their benefits.

The numbers in terms of cost savings, I think Dr. Wilensky, and all of us in the department, use that general range and have a sense that we can make some small increment to cost containment. But primarily we improve the value of the dollar spent.

Mr. LEVIN. Thank you.

Mr. CARDIN. Good morning.

One of the later witnesses will raise the issue of whether we should be focusing the outcomes and effectiveness research and practice guideline program on emerging technologies, rather than existing practices, since it is so difficult to get physicians to change their ways on current medical procedures. Would you comment whether you are focusing on existing or new technologies, and whether it would make sense to put the priorities on the new procedures?

Ms. WILENSKY. Well, I don't know. I think that when we are spending $660 billion for things that are already on the market, we ought not to shunt that aside very much. I would like to assume that whatever's coming down the pike, and its implications, it will be small relative to what we've already got that we're doing.

I do think there's some truth to the fact that we have capabilities of being more careful or more controlling of a new technology

than of an existing technology. We have certainly found that to be true in liver transplants and heart transplants, where we limit the centers as well as the circumstances in which they are occurring. I think that what has now been driving the choice—and since I sit on the advisory group that advises the agency, I have been able to participate—is really a tradeoff of what counts for the Medicare Program, where the dollars and the lives are, and where we are working in areas where we can scientifically make some progress—that is there are certain areas where we feel like we are much more able to make progress than others. I think that if there is a major new technology coming along, trying to do more than just decide whether to cover it or not, particularly if it is likely to have a lot of cost consequences, is reasonable. Given the health spending base of $660 billion or, in the case of Medicare, of $110 to $125 billion, that's pretty fertile ground to go working in. I wouldn't want to tip it too much unless there's a new technology that we think is really going to have a major impact in the Medicare Program, then certainly that would be a good reason to go ahead.

Mr. CARDIN. But if I understand your earlier comments, there's not much hope for great cost savings here, at least initially. Are you saying that you still have hopes of significant savings of that $650 billion?

Ms. WILENSKY. Well, I think again a lot of it depends on the terms relative and significant. I have been hopeful that 5 to 10 percent is a reasonable range when you net everything out, and closer to 10. I don't have any reason for saying that, it just seems like based on the numbers I've been hearing on the appropriateness, that it makes some sense.

I think that in some ways, the assistance we've been getting from technology assessment, and I would use the liver transplant coverage information as an example, is moving us somewhat in that direction, although not entirely. That is, we're doing limited coverage. We're going to cover liver transplants in a certain set of diseases. Now, the exact criteria that would be more like the guidelines would detail when, within the stages of those diseases, does it make sense to do a new transplant, as opposed to just whether or not to do a transplant if you had that disease. I think that if technically, the scientific people thought that they could provide more information, that would be helpful.

The problem with the new technology is likely to be compounded by the problems you get into with any existing guideline, which is that you only know that kind of information after you have some experience. So it would seem to me that while the implications could be more useful with a new technology, the likelihood of having that kind of clinical information is going to be much less since by its nature it will be just coming onboard for acceptance.

So it would seem to me that the two decisions that we always raise which is; how important is it for Medicare in terms of money, and how likely are we able to make some scientific progress in this area, those are going to still be the most important criteria in approving new technologies. So my guess would be a new technology is going to be much harder to prioritize. We have enough trouble figuring out whether it's effective to have that first coverage decision, and having that much more discriminating information about

exactly when does it seem to have payoff, would just seem to me to be much less likely to be available. But I don't know whether the scientific evidence would suggest otherwise.

Mr. CARDIN. Thank you.

Dr. CLINTON. I think there's room for a balance between new technologies and old technologies. There is a handful of examples on both sides. We're concerned, for example, that community, and rural, and small hospitals in general, tend not to use the newer techniques for breast surgery, for cancer of the breast. I'm generally concerned that that new technology is not moving into the surgical field as rapidly as it should.

At the same time, we're concerned about a certain kind of breathing assistance device that we've now demonstrated to be actually harmful, not just neutral, and we have difficulty getting it out of the system fast enough.

Both of those things are changing technologies. One has been around a long time and deserves to be moved out as rapidly as possible, and other things need to be moved in. Other things, particularly the expensive imaging devices, and diagnostic devices, need careful examination quickly. To the extent that we can, we're incorporating that into the patient outcome research teams. We have two that deal with heart disease, myocardial infarction, and chest pain or angina, and those technologies are being reassessed in the real practice through those teams.

So I think we have a good balance of both old things that we have accepted, but need to be reexamined and new things that are coming on quickly. I gave you the gall bladder surgery example a few moments ago.

Mr. CARDIN [presiding]. Thank you.

Mr. LEVIN. If I might just ask one further question.

Let me just ask how two statements are melded. On page 4 in your testimony Gail, you talk about how the UCDS would then subject the extracted clinical data to a series of decision rules that serve as computerized quality screens in order to identify cases needing further review by PRO physicians. So that conjures up the use of all of this data for utilization review in a somewhat systematic fashion.

Then on page 10, it's important the medical community fully understand practice guidelines and adopt them voluntarily. What is the future of all of this effort? Do you see a future where there's so much data that there can be much more effective utilization review, much more effective screening?

Ms. WILENSKY. Yes.

Mr. LEVIN. You do?

Ms. WILENSKY. Yes. I think that we see what we are doing with the UCDS and the algorithms that have been developed with the use of outside experts, as being modified as AHCPR has guidelines. The algorithms are rules of logic that are basically our best shot at guidelines, as practice guidelines are being developed. And that they will provide a way to give information both to the reviewing agency and to the physician so that they can know the likely outcome of patient treatment, based on all of the experience of what's happened in the past when people who have those kinds of symptoms have something done to them or don't.

We move away from this very idiosyncratic review that's typically after the fact in the PRO Program, where a nurse will pick up a record, have some set of objectives or criteria to try to see whether there was something funny that happened so we will be able to look, both before and after the fact, at patterns of care and outcomes and see whether or not the treatment is consistent with all of the information we have. Outcomes-oriented review is much more systematic for the PRO Program and carrier medical review.

I think it will very much change the nature of review away from this idiosyncratic individual review.

Mr. LEVIN. All right, thank you.

Mr. CARDIN. Well, let me thank the two witnesses for their testimony this morning.

The next panel will consist of Dr. Earl Steinberg, director of Johns Hopkins Program for Medical Technology; Dr. Mark R. Chassin, senior vice president, Value Health Sciences; and Dr. Lucian Leape, the Rand Corp.

I want to welcome our three witnesses. Your full testimony has been entered into our record, and you may proceed as you wish. We will be using the 5-minute clock, but you may proceed as you will. We will start with Dr. Steinberg, not just because he is from Baltimore, my home area, but because he is listed first on our panel.

Dr. Steinberg.

STATEMENT OF EARL P. STEINBERG, M.D., M.P.P., DIRECTOR, THE JOHNS HOPKINS PROGRAM FOR MEDICAL TECHNOLOGY AND PRACTICE ASSESSMENTS, BALTIMORE, MD

Dr. STEINBERG. Thank you, Mr. Chairman, and members of the committee, I greatly appreciate the opportunity to testify before you today. As has been mentioned already, the United States now spends $660 billion per year on health care. And despite that, we have devoted comparatively few resources to the evaluation of the effectiveness and outcomes of the health care we provide. The shortsightedness of such a policy has become increasingly clear over the past 2 decades, during which health care costs have skyrocketed with unclear impact on the health status of our citizens.

The Congress has begun to combat this information deficit by providing funding for what is now called effectiveness or outcomes research. As has already been discussed, the flagship of the AHCPR's research program related to this initiative is the patient outcome research team or PORT.

I applaud this initiative and I believe my own experience to date suggests that the PORT's will do much to improve physicians' and patients' understanding of the advantages and disadvantages of alternative approaches to management of particular clinical disorders.

I also am happy to report that in some instances, I believe PORT research, as well as other AHCPR-funded activities—such as the practice guideline panels—will result in health care cost savings. I have detailed one such example related to cataract surgery in my written statement.

It is important for your committee and for Congress, as a whole, to realize, however, that cost-savings will not result from all PORT research. And that PORT research and other AHCPR-funded research—as they are now being conducted—will not achieve the savings in health care costs that potentially could be achieved from a broadened medical effectiveness and outcomes research initiative.

Although there are many reasons for making these assertions, which I have explained in my written statement, I would like to highlight the one that I consider to be the most important; namely, that the vast majority of current clinical and health services research—including that being performed by the PORT's—is targeted at evaluation of established, rather than emerging, medical technologies.

For two reasons such a narrow focus is misplaced. First, many new drugs, devices and procedures become available each year, often at great cost without their appropriate role in clinical practice having been defined. As the biotechnology industry matures, more and more products that are potentially quality-of-care enhancing, but that are cost-increasing, will be brought to market.

The second reason that increased attention should be focused on emerging technologies, is that I believe that it is far easier to shape physicians' use of new technologies than it is to change practices in which physicians have been engaged for long periods of time.

Based on these considerations, I make four recommendations to you. The first is that the current focus of federally funded medical effectiveness and outcomes research, be expanded to include a major emphasis on evaluation of emerging medical technologies, and that additional funding, beyond that currently appropriated for effectiveness research, be devoted to this effort.

Second, I suggest that evaluation of the cost-effectiveness of new drugs, devices, and procedures compared to established clinical practices become a prerequisite for FDA approval of drugs and devices or a component of HCFA's coverage and payment level decisionmaking processes.

This would ensure that the marginal benefits and costs of new technologies would be elucidated before those new technologies become a part of common medical practice. A new rule that would permit use of cost-effectiveness considerations in Medicare coverage decisionmaking will go into effect if Dr. Sullivan approves it.

Third, I suggest that increased funding be devoted to development and evaluation of the effectiveness of various strategies and tools that are intended to change physician behavior. And, fourth, I recommend that efforts be undertaken to increase the accuracy, and in some cases, the detail of data collected as part of the processing of Medicare claims.

In some instances, this will require increased attention to the accuracy of data submitted to HCFA by its local intermediaries and in other instances this will require nothing more than the creation of new CPT codes. Although the AMA is the organization that oversees the development of CPT codes, an indication by Congress—in favor of establishment of new CPT codes for new procedures—would help in this regard.

In conclusion, much can and needs to be done to assess the effectiveness, safety, and cost of new and established medical practices.

It is only through such assessments that we can have any hope of rationally determining which medical practices will improve the health of the public, and which among those can do so at an affordable cost.

I would be happy to answer any questions that the committee may have.

[The prepared statement follows:]

Earl P. Steinberg, M.D., M.P.P.
Director, The Johns Hopkins Program for Medical Technology
and Practice Assessment

Mr. Chairman, and members of the Committee, my name is Doctor Earl Steinberg. I am a health services researcher and a specialist in internal medicine. I currently am an Associate Professor of Medicine and of Health Policy and Management at The Johns Hopkins University. I also am Director of The Johns Hopkins Program for Medical Technology and Practice Assessment, a multi-disciplinary research program jointly sponsored by The Johns Hopkins School of Medicine, The Johns Hopkins School of Hygiene and Public Health and The Johns Hopkins Hospital. The research program I direct is devoted to evaluation of the effectiveness, safety and cost of medical drugs, devices and procedures, and to assessment of the advantages and disadvantages of alternative strategies for managing particular clinical disorders. For the past year and a half I have been the principal investigator of the Agency for Health Care Policy and Research (AHCPR) funded Patient Outcome Research Team (PORT) that is examining variations in the management of cataract, and their relationship to variation in clinical, functional and economic outcomes. I also have spent five years as a member of the American College of Physician's (ACP) Clinical Efficacy and Assessment Committee, the Committee within the ACP that performs technology assessments and proposes practice guidelines. I thus have had considerable experience in evaluation of medical technologies and practice and in the formulation of practice guidelines.

I greatly appreciate the opportunity to testify before you today on the status and potential of medical outcomes and effectiveness research.

The creation of the Agency for Health Care Policy and Research (AHCPR) in December 1989 and the increased federal support since then that has been devoted to evaluation of the effectiveness and safety of various medical tests and treatments have been vitally important steps toward improving the quality and efficiency of the health care provided in this country. As you know, $660 billion are now spent on health care in the United States -- more than in any other country. Even so, our health care spending continues to rise rapidly on an annual basis, at a rate that is about 4% higher than the general rate of inflation.

Unfortunately, despite these massive expenditures on health care, our country has devoted comparatively few resources to evaluation of the effectiveness and outcomes of the health care we provide. As a result, new medical technologies become incorporated into medical practice, often at great cost, without their effectiveness, safety, marginal benefits and costs being well understood.

The shortsightedness of such a policy has become increasingly clear over the past two decades. In numerous instances, new technologies which were expected to substitute for established technologies instead get used in addition to their established predecessors. Often these add-on technologies have little impact on quality of care or patient outcomes.

In addition, dramatic geographic variations in how particular clinical disorders are managed, and in the frequency with which particular diagnostic and therapeutic procedures are performed have been well documented, raising pressing questions regarding whether individual patients are being over- or undertreated. Similarly, incessant increases in health care expenditures, without accompanying evidence that our citizens' health status is improving, have rightly raised doubt about the value of many of the health care services that currently are provided.

In 1988, Dr. William Roper, while Administrator of the Health Care Financing Administration (HCFA), published an article in the New England Journal of Medicine in which he advocated an increased effort to evaluate the effectiveness of medical drugs, devices and procedures. In so doing, he helped launch what is now sometimes called the new "medical effectiveness research initiative", and at other times is called "outcomes research".

As you are clearly aware, medical effectiveness and outcomes research did not begin in 1988; it has been going on for decades. There are, however, several new and important aspects to what is currently called "medical effectiveness or outcomes research". The first is an effort to explore and take advantage of databases and research techniques that traditionally have not been used in evaluation of medical technologies and practices. An example is current efforts to analyze Medicare claims data to evaluate the effectiveness, safety and cost of particular medical practices. When used to evaluate appropriate clinical

research questions, the Medicare claims data are an incredibly valuable and powerful data source. With these data, researchers can assess the outcomes of medical practices as they are typically performed, rather than the outcomes of practices as they are performed in special research settings. In addition, such analyses can be performed at a fraction of the cost of a randomized clinical trial or large scale observational study. A case in point are analyses my PORT is currently performing regarding the rates at which different types of complications of cataract surgery are observed. The results of hundreds of studies have been published on this subject. Most commonly, these results reflect the experience of a single surgeon or medical center over a number of years. None, however, have been large enough to adequately address this issue, and none have been able to demonstrate the effect of changes in surgical technique on surgical complication rates. With the benefit of Medicare claims data, however, which contain data regarding the outcomes of hundreds of thousands of cases of cataract surgery, our PORT can definitively resolve these questions.

In my opinion, there are three other distinguishing characteristics of the current medical effectiveness and outcomes initiative. The first is the increased attention being given to patients' functional status as a treatment outcome, rather than simply addressing whether a patient is alive or dead, or did or did not have a particular event, such as a heart attack. A second distinguishing characteristic is the increased attention being devoted to evaluation and consideration of patient preferences in treatment decisions. The final, and perhaps most important distinguishing characteristic of the current medical effectiveness and outcomes initiative, relates to the substantial increase in resources that the Congress has appropriated to the Agency for Health Care Policy and Research for effectiveness and outcomes research.

As you know, the flagship of the Agency's research program related to medical effectiveness is the Patient Outcome Research Team, or PORT. The PORT approach, to date, has been a stylized one, which involves a multidisciplinary focus on a single clinical problem or procedure, and use of several research techniques, including a comprehensive critical appraisal and synthesis of the existing medical literature, analysis of Medicare claims data, observational studies of variations in practice and related outcomes, surveys of physicians and patients, use of decision analysis to clarify the expected outcomes associated with alternative practices and to identify "optimal" practice, and feedback of the results of these analyses to both physicians and patients.

I applaud this initiative, and as the leader of one of the first four PORTs to be funded, I believe my experience to date suggests that the PORT initiative will do much to improve physicians' and patients' understanding of the advantages and disadvantages of alternative approaches to management of particular clinical disorders.

As a PORT researcher, I also am well aware of the fact that the Congress is hoping that medical effectiveness and outcomes research will lower health care costs, as well as improve the quality of patient care, and that health care savings resulting from PORT activities will become apparent soon.

I am happy to report that, in some instances, I believe PORT research, as well as other AHCPR funded activities, such as the Practice Guideline Panels being funded by the Agency's Forum for Quality and Effectiveness in Health Care, will result in health care cost savings. In the case of the Agency-sponsored Cataract Practice Guideline Panel, being chaired by Doctor Denis O'Day, of Vanderbilt University, for example, the Panel is carefully reviewing the published literature and, to date, has found no empirical evidence demonstrating or suggesting a value associated with use of any of four different pre-operative ophthalmological tests performed to assess a patient's need for cataract surgery or their likely visual function following cataract extraction. My PORT's preliminary analyses of Medicare claims data suggest that these four tests -- specular microscopy, contrast sensitivity and glare testing and potential acuity testing -- were performed at least 250,000 times on Medicare beneficiaries in 1987, resulting in payments by Medicare of over $16 million. Although the Cataract Practice Guideline Panel has not yet submitted or formulated any final practice guidelines, I believe it is likely that the Panel will recommend that, until better empirical evidence of the value of these tests is developed, these tests should only be performed as part of a research study, except in very limited circumstances. This careful analysis, which has involved close collaboration between clinical experts and health services research experts, and

which will have taken almost a year to complete, would not have been performed without a PORT-like initiative.

Despite this example of a potential return on investment of more than 10 to 1, in terms of health care cost savings on each dollar invested in the first two years of the Cataract PORT and the first year of the Cataract Practice Guideline Panel activities, it is important for your Committee, and for Congress as a whole, to realize that cost savings will not result from all PORT research, that most savings that will result may not begin to be realized until one or two years after a PORT has completed its initial five years of work, and that PORT research as it is now being conducted, and Practice Guideline Panel activities alone, will not be sufficient to achieve the savings in health care costs that potentially could be achieved from a broadened medical effectiveness and outcomes research initiative.

I make these assertions for several reasons. First, it is likely that PORT research, and other health services research, will highlight under-utilization, as well as overutilization of health care resources. Second, in many instances, PORTs will find that, although there are no data, or there is only weak evidence documenting the benefits of particular clinical practices, physicians may still believe strongly in the value of those practices -- and, in some of those instances, physicians' beliefs, often based on nothing more than "clinical experience", will be correct. Third, in other instances, medical effectiveness and outcomes research will find strong evidence that a particular technology or practice provides a benefit, but that that benefit is small, and the cost of employing the technology or practice is high. A decision regarding whether to provide or endorse that technology or practice thus becomes based on a value judgment about how much a particular benefit is worth, rather than a scientific analysis of whether a benefit does or does not exist. Moreover, in all of these circumstances, simply demonstrating the benefits or lack of benefits associated with a particular technology or practice may not result in a change in physician behavior. Finally, and perhaps most importantly, the vast majority of current clinical and health services research, including that being performed by the PORTs, is targeted at evaluation of established, rather than emerging medical technologies. For two reasons, such a narrow focus is misplaced. First, many new drugs, devices and procedures, become available each year, often at great cost. Second, I believe it is far easier to shape physicians' use of new technologies than it is to change practices in which physicians have been engaged for long periods of time.

Within the past few years, for example, a new type of radiographic contrast media injected into patients' veins or arteries during procedures such as kidney x-rays, CAT scans and coronary angiograms became available in the United States. These new media are thought to be safer than older media, but they are priced up to 20 times higher than conventional media. Since contrast-enhanced x-rays are performed so frequently, in both inpatients and outpatients, a complete change to the new media would increase The Johns Hopkins Hospital's costs for contrast media by $2 million per year. A complete change to the new media nationwide would increase health care costs by $1 billion per year. Unless further research is performed to evaluate the types of patients in whom these new media actually are safer, and how much safer they are, I predict that health care providers nationwide will feel compelled to use these new media rather than traditional media.

As the biotechnology industry matures, more and more products that are potentially quality of care enhancing, but that are cost-increasing, will be brought to market. Within a year from now, for example, my own institution, The Johns Hopkins Hospital, anticipates a possible increase in its expenditures for pharmaceuticals of approximately $6 million per year due to the anticipated availability of three new drugs which will be found to be safe and effective, but whose actual marginal benefits remain unclear. If we are ever going to control future increases in health care costs, considerably more research regarding the marginal benefits of emerging drugs, devices and procedures will need to be performed before those technologies become firmly established in medical practice.

Based on these considerations, I make four recommendations to you. The first is that you expand the current focus of federally funded medical effectiveness and outcomes research to include a major emphasis on evaluation of emerging medical technologies, and that additional funding, beyond that

currently appropriated for effectiveness research, be devoted to this effort. I believe this evaluative research should be funded through AHCPR, rather than NIH, since the latter's research agenda is focused more on basic science than on evaluation of medical practice.

Second, I suggest that evaluation of the cost-effectiveness of new drugs, devices and procedures compared to established clinical practices become a pre-requisite for FDA approval of drugs and devices, or a component of HCFA's coverage and payment level decision making processes. By so doing, you can ensure that the marginal benefits and costs of new technologies, in each of their potential clinical applications, are elucidated before those new technologies become a part of common medical practice.

It is important for you to understand that, when a technology can be used in the evaluation or treatment of more than one disorder, the cost-effectiveness of that technology must be evaluated for each clinical indication for which it might be used. Evaluation of the cost-effectiveness of magnetic resonance imaging of the brain, for example, does not provide a good indication of the cost-effectiveness of magnetic resonance imaging of the heart or the abdomen. Unless such evaluations become routine, system level interventions designed to make medical practice more cost-effective, such as prospective payment for hospitalizations or capitation, will not have substantial impacts, since the physicians whose behavior you wish to affect will not know what practices to stop performing and which to perform more of.

Third, I suggest that increased funding be devoted to development and evaluation of the effectiveness of various strategies and tools that are intended to change physician behavior. Unless practice guidelines are accepted and followed by physicians in practice, they will have no impact on either the quality or cost of medical practice in this country. Even when physicians endorse particular practice guidelines, they may need tools to help them put those guidelines into practice. The number of practice guidelines related to screening or other types of preventive care, for example, have become so numerous that it is difficult for any physician to keep them all in mind. Over the past year, two of my colleagues at Johns Hopkins and I, as well as a colleague at the University of Chicago, have developed computer software that runs on a simple, hand-held computerized device that asks patients up to 300 pertinent yes/no questions and uses their responses to generate a printout for the patient's physician which lists the preventive practice interventions that are recommended for the patient. Tools, such as this one, will increasingly be needed to help physicians follow accepted practice guidelines.

Finally, I recommend that efforts be undertaken to increase the accuracy and, in some cases, the detail, of data collected as part of the processing of Medicare claims. In some instances, this will require increased attention to the accuracy of data submitted to HCFA by its local intermediaries. In other instances, this will require nothing more than the creation of new CPT codes. Currently, when new technologies and procedures are adopted, new CPT codes related to their use often are not created. As a result, extremely useful information that could, at little cost, help clarify the clinical impact of new technologies does not become a part of insurance claims databases, such as Parts A and B of the Medicare data. For example, one of two different procedures is now typically used to extract a cataract. Unfortunately, both procedures are coded under the same CPT code because a new CPT code was not created when the new procedure came into widespread use. As a result, the Medicare Part B data cannot be used to help clarify the comparative complication rates associated with each procedure.

In conclusion, much can and needs to be done to assess the effectiveness, safety and cost of new and established medical practices. It is only through such assessments that we can have any hope of rationally determining which medical practices will improve the health of the public, and which among those can do so at an affordable cost.

I would be happy to answer any questions that the Committee may have.

Mr. CARDIN. Thank you, Dr. Steinberg.
Dr. Chassin.

STATEMENT OF MARK R. CHASSIN, M.D., M.P.P., M.P.H., SENIOR VICE PRESIDENT, VALUE HEALTH SCIENCES, INC., SANTA MONICA, CA

Dr. CHASSIN. Thank you, Mr. Chairman, and members of the committee, for inviting me here this morning. I would like to address four key questions about practice guidelines this morning. The first is, can guidelines be developed in the absence of scientific data establishing the effectiveness of health services? Some observers argue that practice guideline development must wait for the creation of a new scientific data base on effectiveness. I disagree strongly.

I believe that practice guidelines can, and should, be developed today despite the paucity of rigorous scientific efficacy data. All guideline development basically consists of two steps, summarizing known effectiveness and efficacy data and then adding expert clinical judgment. One major goal of guidelines is to establish boundaries beyond which care is clearly inappropriate.

I believe that for this purpose guideline developers will never be able to rely on the availability of scientific efficacy data. To prove, rigorously, that a health treatment is inappropriate would require exposing patients to that treatment when everyone agrees it is likely to do more harm than good. Such studies will simply never be done. It seems to me, therefore, almost a logical certainty that in order to establish what constitutes inappropriate care guidelines will always have to rely principally on expert clinical judgment rather than on scientific efficacy data.

The second question is, will guidelines improve quality of care? The answer is, yes, but only if great care is taken to apply them wisely. Research has taught us that some methods work and some methods don't. The methods that work require careful thought and planning and must be supported by a significant commitment of resources. The method that has been repeatedly shown to be ineffective, for example, is mailing guidelines to physicians. And, yet, how do specialty societies communicate their guidelines? How does NIH communicate the results of its consensus conferences—typically by publishing them in clinical journals, which are mailed to physicians.

To be successful, I believe, AHCPR should devote a substantial share of its resources to implementation programs that pay attention to the lessons of the past.

The third question is, will guidelines save money? Asking this question is a little bit like asking do chemicals cause cancer—some do, some don't. With guidelines, the answer depends on what problem the guideline is directed at. Broadly speaking, there are three different kinds of quality problems in American medicine—overuse, underuse, and misuse. If guidelines focus on problems of overuse,

propriateness of 27 medical and surgical procedures prospectively. Our guidelines are the most clinically sophisticated in use today. We created them using methods first invented by the Rand Corp.'s appropriateness studies in the 1980's.

Our clients currently include payers, utilization review companies, and HMO's across the country. In less than 2 years our system now covers about 8.5 million Americans. We use a two-stage review process of preprocedure review that begins with the application of explicit guidelines as screening criteria. They allow a review nurse to approve cases that represent appropriate reasons for procedures. All potentially inappropriate cases are referred to a physician for individual case review.

Our experience is, that on average, about 10 to 15 percent of cases are judged inappropriate at the end of the second stage of review. Some of our HMO clients have reported substantial sentinel effects in addition to the rates of inappropriateness determined during the review process itself. Our clients report rates of return on investment as high as 6, and 8 to 1.

Our review system is an efficient, functioning example of practice guidelines in action. We do not operate the system as a black box. Physicians under review are informed about the guidelines in advance, and always know exactly why a particular case has been found not to meet criteria for appropriateness.

The fourth question is, how well are we doing currently in producing guidelines? The answer is, not too well. Many currently available guidelines are plagued by serious methodologic problems. They often are far too simplistic clinically and are met with ridicule or apathy by practicing physicians. They are often written in such vague and ambiguous terms that they can't be applied in any consistent manner.

Users of guidelines do not have a reliable means to judge their quality—a problem that will get much worse as the volume of guidelines grows. These problems can be solved.

I believe we must increase the resources devoted to guideline development. We must also create a way of evaluating guidelines that will encourage the production of guidelines of high quality and discourage shoddy efforts.

On the whole, I am very optimistic about our ability to have a major beneficial impact on health care quality through the use of guidelines. We know how to produce good ones now, we know how to make them effective, and we know how to use them to reduce costs.

We need to get on with it.

Thank you, very much.

[The prepared statement follows:]

Statement Submitted to the House Ways and Means Committee
Subcommittee on Health
Practice Guidelines and Quality of Care

Mark R. Chassin, M.D., M.P.P., M.P.H.

April 30, 1991

A number of different forces came together to produce the current public policy emphasis on clinical practice guidelines and on research directed at measuring effectiveness and outcomes. The costs of health care continue to increase. In the late 1980s, this chronic problem started to put on a somewhat different face. As the depth of our ignorance concerning the efficacy and effectiveness of health services became more widely understood, the cost issue confronting health policymakers began to change to one of value. The concern focused less on the number of dollars we spend on health care and more on the question of whether these sums produce benefit commensurate with their amount.

This concern led Congress to establish a new federal agency with new mandates to improve our knowledge base on effectiveness and outcomes and to facilitate the development and dissemination of clinical practice guidelines. Where do we stand today on guidelines and the new research activities? How do they relate to each other? What will their likely impacts be? How can we realize their maximum potential?

Relationships Among Guidelines, Outcomes, and Effectiveness

The new emphasis, backed up by new funding, on research targeted specifically at improving our understanding of the effects of health care on patient outcomes has been extremely beneficial. Given the enormity of these gaps in our knowledge, however, even more of an effort is needed. Continued support for this research effort is vital, and it should be expanded to include support for the randomized controlled clinical trials that will be necessary to answer some of the more thorny efficacy and effectiveness questions.

The guideline development process synthesizes existing research data and expert clinical judgment. It results in statements that describe the specific clinical circumstances in which particular health treatments should be done, when they shouldn't, and when we just don't know enough to provide any guidance. Over time, the new research effort focusing on outcomes can be expected to supply an ever-expanding volume of scientific data to inform guideline development.

Because this research will take years to produce findings, we should anticipate that its impact will not be instantaneous. It will take many years before the cumulative impact of this research effort becomes significant. Clinical practice guidelines can have a much more immediate impact, and our efforts to develop and implement guidelines should not be predicated on waiting for the results of additional research.

Indeed, I would argue that we must proceed more vigorously to develop guidelines over a wider array of health care services even in the absence of scientific data on efficacy. Physicians confront the problem of absent scientific data every day as we care for patients. We cannot tell patients that no recommendations can be made for their problems because we have no research data to guide that advice. Physicians can benefit enormously from guidelines, especially in those clinical areas where clinical research fails to provide clear answers.

Two lines of reasoning suggest strongly that guideline

development must proceed in parallel with the research effort. First, the immense size of the research task to produce data on effectiveness means that for the foreseeable future we will confront the same situation we do now: insufficient scientific data with which to judge the effectiveness of most health practices. We have two choices. We can avoid developing guidelines where we lack scientific efficacy data and thereby miss a major opportunity to assist physicians in practice. Or, we can press on using the excellent guidelines development techniques we have to attack the problem. Clearly, I strongly favor the latter approach.

The other important reason to pursue vigorously the use of guidelines is that for certain purposes, it is likely that research will never produce scientific data. Specifically, one important use of guidelines is to define circumstances under which health services ought not be provided. It is most unlikely that research will be undertaken to prove that an inappropriate reason for rendering a health service really results in poor patient outcomes. Such a study would require exposing patients to a health service when everyone agrees it should not be provided. No responsible human subjects protection committee could approve such a research protocol, nor could any funding agency support it. Such studies would almost always be unethical. Guidelines built on expert clinical judgment are virtually the only way to approach the problem of defining inappropriate care.

Uses of Practice Guidelines

At present, I believe a consensus exists among all major constituencies (organized medicine, employers and other payers, health plans, health services researchers, etc.) that practice guidelines should be developed. The consensus breaks down, however, over the issue of how guidelines should be used. Consequently, we have given very little attention to planning systematic and effective means of implementing guidelines. I believe that this lack of attention is a major obstacle in the way of realizing the maximum potential impact of practice guidelines.

There are many potential beneficial uses of guidelines. These begin with educational applications. Guidelines have been used for decades in physician education, both at the undergraduate level and for continuing education of practitioners. While most observers usually think in terms of guidelines educating physicians, there is no reason that they could not be adapted to form the basis of an effective means of patient education. Some very simple patient care algorithms have been marketed to consumers. (1) Significant resources will be required to adapt the most sophisticated guidelines for patient or consumer use, but the task is eminently feasible.

Guidelines are already being used to help make payment decisions, and they will become much more widely used as more and better quality guidelines are developed and as methods to apply them effectively are worked out. At present, guidelines are used to assist decisions on when elective procedures and hospitalizations are medically necessary, when procedures may be done without an overnight hospital stay, and when patients no longer require a hospital level of care.

Another common use of guidelines occurs during local programs of hospital or medical group quality assurance and quality improvement. In these settings, local physicians develop their own guidelines for how they believe care should be rendered in a particular clinical circumstance, review a sample of medical records to determine the extent to which the guidelines were met, and attempt to correct any problems they find. These processes are typically plagued by an inability to develop high quality guidelines, the kind that avoid the problems with most current guidelines that are discussed below.

Much less common today, but entirely feasible with well-constructed, sophisticated guidelines is the use of guidelines to evaluate physician performance. Some innovative health plans already use guidelines (usually simple ones) to assess the quality of care provided by individual physicians or groups. Such assessment could be done on a voluntary basis, like the program tested by the College of Family Physicians of Canada. (2) With the spread of managed care, however, it is more likely that as efficient systems for applying guidelines become available, the assessment will be imposed by health plans. These assessments can be used to evaluate membership in preferred provider organizations, hospital staff credentialing, and medical licensing.

Finally, well-constructed guidelines will be a boon to health services research. Most current health services research studies must invent their own guidelines or quality of care criteria. Measuring quality will be vastly facilitated by the availability of sophisticated, well-constructed practice guidelines.

Problems with Existing Guidelines

The previous section described a number of potential uses for guidelines and was based on the assumption that only guidelines of high quality would be employed in these settings. The Institute of Medicine in a recent report described a series of attributes that define high quality guidelines. (3) It is unfortunately true that the vast majority of current guidelines do not possess even a fraction of the attributes identified in the IOM report. The use of poor quality guidelines risks adverse health effects if they are employed to assist in payment decisions and ridicule if used in physician education. The most common problems with existing guidelines are:

1. The methods by which they are developed are unscientific.
2. They are clinically simplistic.
3. They are too often couched in vague and ambiguous terms.
4. Users cannot judge the quality of guidelines.

All guideline development processes consist of two components: reviewing clinical research literature and bringing expert clinical judgement to bear on the topic at hand. Many guideline development processes fail to document literature review methods, omitting to describe whether critical analysis of research designs was done to assess generalizability. Most methods use undocumented consensus processes to add expert judgment that are subjective and not quantitative. Guidelines developed by specialty societies typically lack input from a broad representation of all groups of physicians who care for patients with the particular clinical problem addressed by the guideline.

Too often, guidelines prove irrelevant to clinicians because they fail to encompass all of the clinical factors physicians consider important to patient decision making. One PRO uses the following criterion to assess the appropriateness of abdominal hysterectomy: "cervical intraepithelial neoplasia." This term is a generic description of a potentially premalignant lesion of the cervix. Other important factors that are crucial to the decision of whether hysterectomy would be appropriate in this setting include the age of the woman, whether she strongly desires to preserve future fertility, previous diagnostic and therapeutic interventions, and the severity of the lesion. It is impossible to consider the appropriateness of hysterectomy in this setting without assessing these other clinically vital issues.

Many guidelines are hampered by the vagueness and ambiguity with which they are constructed. One PRO's criteria for approving carotid endarterectomy included the following: "History of ... transient speech dysfunction ... and diagnostic angiography confirming an atherosclerotic lesion in appropriate carotid

artery." The term "transient speech dysfunction" is far too vague to communicate the specific neurologic abnormalities that might represent transient ischemic attacks and might thus be caused by carotid disease. The term "atherosclerotic lesion" can refer to a completely insignificant plaque or a major obstruction block nearly all blood flow through the artery. This problem is very common and is a major source of unreliability in the application of practice guidelines.

Given the multiplicity of sources for guidelines, it is important to create some mechanism to evaluate their quality. At present, users must do this job on their own, individually. With the growing number of guidelines and the great potential for conflict among them, this task will soon become impossible for the individual user.

These problems are all soluble with existing methods of guideline development and evaluation. They must be addressed before the beneficial impact of any of the uses outlined above can be fully realized.

Can Guidelines Improve Practice?

The answer to this question is a qualified yes. Most of the literature that addresses this question focuses on the educational use of guidelines to influence physician behavior. The message from this literature is clear and consistent. Some methods work, and some do not. I have discussed these issues elsewhere (4,5) and will summarize them here.

The components of an effective educational use of guidelines are:

1. Well-constructed, focused guidelines.
2. Data on physician performance with respect to the guidelines.
3. Guidelines presented to physicians face-to-face.
4. Reinforcement following initial presentation of guidelines.

The first requirement for guidelines of high quality ensures that the clinical substance of the guideline will be perceived by physicians as relevant to their practices. Guidelines plagued by the problems described previously will not be seen as helpful or worthy of attention by physicians.

Many studies have shown that providing physicians with data from their own practices on how well they currently comply with guidelines markedly enhances the impact of the guidelines. Similarly, a number of studies have demonstrated that physicians respond to a far greater degree if the guideline information is presented to them at a face-to-face meeting by another physician. This effect is further enhanced if the physician is well-respected in the community. The least effective method of changing physician behavior using guidelines is to put them in the mail. A large number of studies have demonstrated that mailing guidelines to physicians has no impact on their practices. Finally, another repetitive theme in this literature is the tendency of behavior changes to wane over time, indicating the usefulness of periodic reinforcement of the guideline's initial message.

The implication of these observations is that the impact of guidelines cannot be assumed, particularly when they are planned to be used educationally. They can be a significant force for quality improvement, but such interventions must be carefully planned and implemented with sufficient resources to incorporate the lessons of the past. To date, very little attention has been devoted to the problem of implementation. Specialty societies typically rely on clinical journals (delivered in the mail) to

communicate their guidelines. Far more attention and resources must be devoted to the problem of how to construct effective guideline implementation strategies and programs.

Will Guidelines Save Money?

The answer to this question depends on what problems the guidelines focus. Three fundamentally different kinds of quality problems exist in American medicine: overuse, underuse, and misuse. Overuse refers to the provision of a health service under circumstances when expected risks outweigh expected benefits. Underuse is the failure to provide a health service when it would have proven beneficial to the patient. Misuse occurs when a health service has been correctly chosen for a patient (i.e., it would have been beneficial had it been performed skillfully) but performed ineptly, leading tc avoidable adverse outcomes.

If guidelines focus on problems of overuse, it is very likely that cost savings can be realized. The experience of my company bears this observation out. Value Health Sciences develops and applies sophisticated guidelines for the appropriateness of medical and surgical services to precertify elective procedures. Our clients include major commercial insurers such as Travelers and Principal Financial Group, Blue Cross and Blue Shield plans, utilization review companies, and HMOs. Our precertification system now reviews care for more than 8.5 million Americans. Using a two-stage process of review that includes application of guidelines as screening criteria followed by individual consderation by a physician, we have found 12%-15% of cases to represent clinically inappropriate care at the end of the second stage of review. Our clients regularly report rates of return on investment of 6 or 8 to 1. Some of our HMO clients have measured sentinel effects that have led to overall decreases in the use of specific procedures that are several times greater than the denial rates observed during the review process for those procedures.

Our approach to preprocedure review requires scientifically developed, clinically detailed guidelines. Because no other groups are developing such guidelines in sufficient number or with sufficient rapidity, we apply state-of-the-art health services research techniques to develop our own. The system does not operate in secrecy. Physicians under review are informed about the guidelines in advance and always know exactly why a particular case has been found not to meet criteria for appropriateness.

Our review system is a practical, functioning example of practice guidelines in action. We have solved the large number of logistical problems that need to be addressed in making sophisticated, clinically detailed guidelines work to ferret out inappropriate care. By developing and implementing guidelines directed at the problem of overuse, we have demonstrated the ability to improve quality and reduce costs at the same time.

On the other hand, if guidelines were to focus solely on problems of underuse, it is very likely that costs would increase. A focus on problems of misuse would have unpredictable effects on cost.

Prioritizing Guideline Development

How should we decide what clinical areas should be the subject of guideline development? If the goal of developing and promulgating guidelines is to improve quality of care, then ideally one would first collect data to understand the amount of harm conveyed by all existing quality problems. With these data, one could order quality problems in descending order of the burden of harm they inflicted and develop guidelines for the most burdensome problems first.

The Institute of Medicine's Committee to Design a Strategy for

Quality Review and Assurance in Medicare reviewed this issue, commissioning a paper to summarize existing knowledge on the burden of harm represented by each of the three major categories of quality problems: overuse, underuse, and misuse. (6) The Committee concluded that current data are insufficient to allow such determinations to be made and recommended that Medicare's quality assurance mechanisms devote attention to all three categories of problems.

The absence of data does not absolve us of the need to make decisions; we must choose specific clinical areas in which to develop guidelines. I believe that current consensus methods could be used to generate best current thinking about the burden of harm accounted for by the most important quality problems. Such an exercise could provide important guidance to the Agency for Health Care Policy and Research, to specialty societies, and to the health services research community as they deliberate the problem of selecting topics for guideline development.

Of course, one might have a different goal in mind for guidelines than quality improvement. Cost savings suggests itself as another candidate. With cost savings as the goal, a very different priority list would be constructed, one that might start with a consensus process to estimate the dollar burden of overuse. At the federal level, if different constituencies have different goals for guidelines, such differences must be resolved or at least recognized to mitigate the adverse effects of differing expectations for guideline development and dissemination programs.

Conclusion

Practice guidelines can be a very effective tool for quality improvement in medicine. If they focus on problems of overuse, they can improve quality and reduce costs simultaneously. We must increase our efforts to produce scientifically and clinically sound guidelines at the same time as we increase our effort to produce a greater quantity of data that assess the effectiveness of health services.

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Mr. CARDIN. Thank you for your testimony.
Dr. Leape.

STATEMENT OF LUCIAN L. LEAPE, M.D., ADJUNCT PROFESSOR OF HEALTH POLICY, HARVARD SCHOOL OF PUBLIC HEALTH, AND CONSULTANT, RAND CORP.

Dr. LEAPE. Mr. Chairman, and members of the committee, thank you for the opportunity to present before you. I would first like to compliment Dr. Clinton and his colleagues at the agency for Health Care Policy and Research for the excellent job that they have done in getting the process of practice guideline development moving.

When people talk about practice guidelines they usually talk about ways to influence physician behavior, and they are concerned about how physicians will respond to them. I would like to consider with you, for a moment, guidelines from the patient's point of view. It is the patient, after all, who we, you and I, are concerned about helping.

When I am the patient coming to the doctor with a serious illness, I want three things. First, I want him to have readily available—not necessarily in his head but readily available and at his fingertips—all of the relevant scientific information and expert opinion on what works best for the condition I have.

That is, if I have coronary artery disease and I have angina, I don't want him to tell me, in general, what works for angina, I want him to tell me what works for somebody my age, my gender, a patient who has my severity of angina, a patient who has the same amount of blockage of the arteries as I have, a patient who has the same kind of heart function, treadmill tests, high blood pressure, etc. This is highly specific information and unless the information is available at that level of specificity, what he tells me isn't of great value to me.

Second, I want him to provide me with the pros and the cons of the alternative forms of treatment. If surgery is being recommended—what is the probability of success, what is the probability of my dying? If there is another alternative—what are the probabilities of its success, and what are its risks?

Then third, I want him to fully inform me of his level of certainty about that information. That is, if the experts agree, I want to know that. If the experts don't agree, I really want to know that.

So I want to know what works for my specific condition. I want to know what the pros and cons are, the probabilities, and I want to know the certainty. Now, of course, I want a lot of other things. I want compassion and understanding. I want help in making my decision and so forth, but first, I want the facts. That is when I go to a doctor, that's what I expect him to deliver.

That's what practice guidelines are designed to do. The purpose of guidelines is to distill and sort out from hundreds, literally thousands, of scientific articles, the information the physician needs to determine whether something works. The question is very simple. Does it do what it is supposed to do, and what is the evidence? If you don't have the evidence, what is the best informed expert opinion?

Properly done, guidelines also provide the probabilities of the outcomes. They give you numbers that say, here's what the chances are. Again, if the scientific data is there, that's what we want. If it's not, we want the best informed opinion.

And properly done, guidelines also provide a reading on how sure the doctors are about those outcomes. They let us know if there's a consensus or that experts disagree. In short, guidelines help us to ensure that medical care is appropriate.

Now, a payor, insurance company, or the HCFA, wants the same thing. They want to know that the procedure works and they want to know what the probabilities of success are. But I should point out that if a procedure does not have a significant benefit for a particular indication, it shouldn't be provided and certainly we shouldn't pay for it.

There are some absolutes in this. And it is possible to identify those indications for which a given procedure is totally inappropriate. We should be willing to say that, and we should be willing to act upon that.

Now, the question is, How do we get those guidelines? Guidelines that work, guidelines that really sort out effective from ineffective care are not easy to develop. They are complicated, they are detailed, they are comprehensive, they are specific, they have to specifically identify appropriate and inappropriate care, and most of all, they must be based on rigorous analysis of scientific evidence, evaluated by experts, and have the process carried out through a fair and open process.

It is important to emphasize that very few of the 1,100 or so guidelines that you have heard about, meet those criteria. The real danger we have, at the present time, is that in our hurry to implement guidelines and try to make an impact that we will go with poor guidelines and they will have no impact. Therefore, the whole process and the whole concept will be undermined because we have done it poorly.

I think the most important thing we have to do now is to do it right. To get where we want to be, to give guidelines the opportunity to have the impact they can have we need to do three things.

First, we need to significantly expand the guideline effort to simultaneously produce a number of guidelines, 15 or 20 sets per year for at least 5 years, while at the same time, validating the guidelines, improving the methodology, and evaluating the effectiveness of guidelines in improving practice. We need to get some guidelines into use, but we need to get the right kinds of guidelines into use.

The agency has done a good job under severe time constraints, but they have pursued an individual ad hoc approach which we think will not end up giving us the kind of information we need, that a comprehensive and coordinated effort that looks at all aspects of guideline development would do.

Second, we need to involve both researchers and practicing physicians in organized medicine in this effort. The academicians are needed to improve the methods, and the organized medicine is needed to participate in the process and to ensure that guidelines are relevant to clinical practice. Organized medicine has been left out of the process so far and that is curious because the American

College of Physicians, the American Heart Association, the American College of Cardiology, and others were the pace-setters in the guideline movement, long before the agency existed. They should be part of the process now.

An important question is whether we are going to have Government guidelines or whether the Government is going to encourage and support the medical profession in its effort to develop guidelines?

The important question is, What's the way to improve quality of care? When a doctor finds his judgment is questioned by a payor, he questions the payor's judgment. When a doctor finds his judgment is different from that of the American Heart Association, he questions his own judgment. When a physician finds his judgment is in conflict with the payor, he looks for ways to get around it. When he finds his judgment is in conflict with his peers, he begins to question the value of his own judgment.

If you want to change physician behavior, practice guidelines must be developed and they must be disseminated and approved by physicians. We need to get organized medicine into the act, as well as the rest of us.

Our reading of the legislation is that the intent of Congress was that the agency set the standards for guidelines, and set the standards for the process of guidelines, and encourage and support their development but not to actually do them, themselves. We think this is appropriate and we also think it is appropriate for the agency to oversee and monitor the process to make sure that the standards are met.

Finally, we think this effort, if it is to succeed, requires a substantial increase in funds and a change in the method of funding to carry it out. A coordinated effort requires a coordinated and cooperative arrangement, a public-private enterprise in which contracts are awarded from not just a simple project, or a single set of guidelines, but a comprehensive program on a competitive basis that will result in the advancement of the methodology at the same time, as we produce guidelines.

The amount needed, we estimate $10 to $20 million a year, is a small fraction of what is currently spent on health care. I agree that we do need a crash program, and $20 to $30 million a year is not a very large sum if we can cut the 5 or 10 percent of inappropriate use in half.

We think practice guidelines can do that.

Thank you, Mr. Chairman.

[The prepared statement follows:]

STATEMENT OF

Lucian L. Leape, MD
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IMPROVING THE QUALITY OF CARE: PRACTICE GUIDELINES

Mr. Chairman, I am Lucian L. Leape, Adjunct Professor of Health Policy at the Harvard School of Public Health and a Consultant to the RAND Corporation. For twenty years, I was in the fulltime practice of pediatric surgery, but for the last four years I have worked with colleagues at the RAND Corporation on methods for developing and testing practice guidelines because of my conviction that they offer the best opportunity for eliminating unnecessary and inappropriate care. I come before you today to share with you our concerns and our hopes regarding the role of the government in the guideline development process.

The creation by Congress, under OBRA 89, of a new Agency for Health Care Policy and Research was a watershed event. For twenty years, the government, payers, hospitals and physicians had struggled, at great effort and at great expense, to measure and improve the quality of health care. These efforts were often unsuccessful because they were initially based on false assumptions: that the standards of care were well-developed, well-known, and easily applied. None of these assumptions were true. We set out to measure quality before we defined it.

But in the 80's doctors and others in the health services research community made great progress in developing methods for measuring the quality of care, and in 1989 Congress responded to their entreaties to provide increased federal funding to advance this effort. New Funding was primarily directed toward outcomes research, with a lesser amount earmarked for the development of practice guidelines.

The relationship of practice guidelines to outcomes research

The purpose of outcomes research is to provide evidence of effectiveness. It is a new approach that will provide data to supplement that obtained by the traditional methods of randomized clinical trials, which are expensive and difficult to carry out.

To have an impact on the quality of care, the evidence from outcomes research and randomized clinical trials needs to be incorporated into the decision making of physicians. An important step in that process is translating the evidence into recommendations for practice. That is what practice guidelines are intended to do. And that is what practice guidelines can do, and will do, if they are properly developed and disseminated. So, outcomes research and practice guidelines are complementary strategies for improving the quality of care.

The activities of the Agency for Health Care Policy and Research

The legislation concerning practice guidelines directed the Agency to do five things: arrange for the development of guidelines, standards, the review criteria; establish standards for methods to be used in the guideline development process; promote the dissemination of

guidelines; use the guidelines to improve the quality of care provided under Medicare; and evaluate the impact of guidelines on the cost and quality of medical care.

Seventeen months later, where are we? What progress has been made in accomplishing these objectives?

In specifying that the Agency, through the Forum for Quality and Effectiveness in Health Care, was to "arrange for" the development of guidelines and standards, Congress made it clear that the federal government would not itself be in the guidelines development business. The Forum had two options: to contract with public or nonprofit organizations to develop guidelines or to convene expert panels to develop or approve guidelines. Given the limited funds ($2 million) provided for this purpose, the Agency understandably chose the latter course. We understand that the first of these guidelines will soon be completed and ready for testing.

Progress toward the second charge, to establish standards for methods to be used in the guideline development process, has been faster. Wisely, the Forum turned to the Institute of Medicine which convened an expert panel to assist them, This panel has developed a preliminary set of attributes of good guidelines and set out some of the criteria for their development. The IOM is now conducting a more comprehensive 18 month study of the process of development, implementation and evaluation of guidelines.

The IOM recommendations endorse several fundamental principles of guideline development that we believe are essential: for credibility, guidelines must be based on thorough evaluation of the scientific evidence of effectiveness, the process of developing guidelines must be explicit, open, and fully described, and the expert panels must not be restricted to those who provide a service, but must include other experts and interested parties. These are the distinguishing characteristics of the methodology developed at RAND and used in our initial prototypes. While the importance of these characteristics may seem obvious, few of the previously developed guidelines met these criteria.

We commend and support the progress the Agency has made toward establishing standards for guideline development. Setting standards for standards is a critical feature of the process and a necessary first step in implementing the Congressional mandate. We look forward to further recommendations by the IOM.

Given the short timetable and limited funding, the Agency had little choice but to commission the development of several individual sets of practice guidelines. But, if practice guidelines are to become a reality and realize their potential to have a significant impact on the quality of health care, a much larger effort is required. A broader and more comprehensive approach is needed to simultaneously produce a larger number of guidelines and advance the methodology of guideline development. As the IOM report points out, guideline development and implementation is not a simple process. It is not likely to be advanced by piecemeal efforts by isolated researchers and administrators who do not, and cannot, by themselves

address all of the important issues in methodology, implementation, and evaluation. The full powers of the research community and the professional societies need to be focused on this effort to accomplish the goals intended by the Congress. This must be a coordinated effort, a comprehensive effort, and a program of some magnitude.

The final objectives of the legislation, dissemination, use, and evaluation of practice guidelines has yet to be addressed, but the Agency has called for research applications to address these issues.

Where do we go from here?

What is the long term plan? Who will improve the methodology and produce the dozens of sets of guidelines that are needed? We believe that the practice guideline development initiative is crucially important if the advances in medical research are to be made available to the public and if inappropriate and unnecessary care is to be curtailed. We need to develop - as a public-private cooperative enterprise - the institutional capability to develop guidelines, to improve the methodology, to maintain, revise and update the guidelines, and to deal with variations and exceptions as guidelines are incorporated into practice.

Doctors in many groups, academic and professional, but most especially the medical specialty societies, had developed many sets of practice guidelines before the new Agency was formed. However, this initiative has forced them to focus attention on the process - it is more complicated than many had thought - and on the standards for that process. That alone justifies this new program. Thanks to the debate about the standards that has already taken place under its auspices, the Agency is beginning to have an impact. More than ever before, there is now an awareness of the need for rigor, openness and balance in the guideline development process. We need to develop guidelines anew, but we can build on what has already been learned.

The guideline development process has to be led by physicians. The doctors with the expertise are in the leading medical schools and in the professional specialty societies. If practice guidelines are to be developed of appropriate quality, and in significant numbers, it is necessary to develop institutional capabilities to develop and maintain them, and this must be a cooperative venture between academicians and clinicians, between medical schools and organized medicine. While the technical responsibility and expertise necessarily reside with these groups, the Agency, through the Forum, must continue to exert its oversight and standard setting function if the development of this capacity is to occur. And it must fund it.

The major share of new funds for the Agency has been given to outcomes research. While this funding is appropriate because of the crucial need for more scientific evidence of effectiveness, it is important to recognize that this vast effort will take years to produce results, and that the evidence so obtained will apply to only a small fraction of conditions and procedures. And, when that evidence is in, it will still need to be translated into practice guidelines to make it accessible for physicians.

Guidelines, on the other hand, can be produced in a much shorter time frame, and have, therefore, the potential to lead much more quickly to improvement in the appropriateness of use of a large number of services and procedures. And, as noted earlier, these are complementary functions. Guidelines are needed to translate science into practice - now, as well as after outcomes research findings are available.

It should be noted that practice guidelines address not only the problem of overuse of services; they also offer the means to get at the problems of underuse, denial of essential services to those who need them. Often neglected in our concern with cost-containment, many disadvantaged groups in our society have been shown to receive far fewer medical services. Guidelines and appropriateness criteria provide a means to identify such underuse.

While the methodology for guideline development can be improved - and should always be the object of scrutiny and refinement - current methods are adequate to accomplish a great deal. We know how to implement the basic principles endorsed by the IOM committee. Within the past year, researchers at RAND and the Academic Medical Center Consortium have produced detailed guidelines for six operations and procedures, and are now beginning to test their usefulness in assessing quality and in changing medical practice. With adequate funding, this effort could be expanded to producing 10-20 sets a year, so that within five years we could have 50-100 sets of practice guidelines that would apply to the operations, services, and procedures that account for more than half of health expenditures.

While fostering the development of guidelines, a comprehensive program could, with adequate funding, also advance the methodology of guideline development so that we improve the process while we produce the product. A coordinated effort could thus simultaneously develop guidelines, improve the process, implement them, and evaluate their effectiveness at changing physician behavior. The costs of such an effort, to produce guidelines, do the essential research to improve the product, and evaluate their effectiveness in practice, is about $1,000,000 per set of guidelines, or, for 20 sets of guidelines, an expenditure of about $20 million a year. We think a lesser effort would be ill-advised, for it will fail to demonstrate the potential of practice guidelines to have a substantial impact on the appropriateness of care. This $20 million should increase to $50 million within a few years as institutional capability increases. A mechanism is needed to insure that this process occurs rapidly so that practice guideline development takes place now, not five years from now.

Who should develop guidelines?

We agree with the intent of Congress expressed in the enabling legislation that guideline development is not an appropriate function of either the government or the for-profit sector. Both, we hope, will use guidelines that are developed by the profession, but not the other way around.

If the government is not to develop guidelines, then who is to muster the resources to advance guideline development and implementation? Clearly, two parties must play essential

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roles: clinical experts and researchers. The experts belong to the professional specialty societies, and the researchers are in the academic medical centers and research institutions. These parties must work together to advance the guideline development and implementation process.

The RAND/Academic Medical Center Consortium/AMA Appropriateness Initiative was formed specifically for that purpose. The RAND Corporation is an independent, not-for-profit research organization, and the AMCC is a consortium of 12 leading medical centers dedicated to improving quality of patient care. The AMA has taken the lead in an effort to coordinate and facilitate specialty societies' development of practice guidelines based on the appropriateness guidelines developed by RAND and the AMCC or on similar methods.

We think the time has come for the Agency to launch a much more substantial, coordinated effort in the private, non-profit sector to carry out its mandate. This could be most readily facilitated by the award, on a competitive basis, of a contract to advance the production, research, and implementation of guidelines. In addition to the RAND/AMCC/AMA Appropriateness Initiative, other non-profit consortia would respond to such an opportunity, and such competition should be welcomed and encouraged to insure that funds are wisely spent. But it is essential that there be a commitment to a complete package that includes the development of at least 15 sets of guidelines, research on methodology, and implementation and evaluation of the impact of guidelines on practice. The Agency should embark on a program that extends over 4-5 years. Single sets of guidelines developed by isolated efforts and individual research grants will not do the job, nor will they lead to the development of the institutional capacity and cooperative arrangements that are needed.

Implementation strategies

How will practice guidelines be implemented, and, once implemented, will they make a difference? Wisely, the Agency has recently issued a call for studies of approaches to implementation of guidelines. While much is known about how doctors integrate new information into their practice, much more remains to be learned. We need to look carefully at alternative methods of implementation, using as our criterion of success demonstrated improvement of the appropriateness of care.

While there is more than one way to implement guidelines, the most important factor in the success of any method of implementation is the quality of the guidelines themselves. We are confident that guidelines will be accepted and used by physicians if they are valid, credible, and authoritative. Obviously, guidelines must be valid, and must be perceived by physicians to be valid if they are to be used. The recommendations must make clinical sense and be consistent with scientific evidence where it exists. And guidelines must be re-validated when new evidence is available.

Credibility depends on **process** - the process by which guidelines are developed - and **expertise** - the quality of the experts who participate in the panels. Several aspects of the

process are critical: First, the guidelines must be based on an exhaustive analysis of the scientific evidence of effectiveness. Second, the process must be open: the methods by which the expert panels arrive at their decisions must be explicit and completely described so that any interested party can understand how the group decisions were reached. There is no place for "black boxes" and covert judgments. It is not satisfactory for experts to sit in a closed room and issue consensus judgments. All those who are affected by guidelines have a right to know how those judgments were reached and how much of a consensus of experts they truly represent.

Third, bias must be minimized by using expert panels composed of more than just those who perform the procedure. Other essential experts are those who also care for or refer patients for the service as well as other knowledgeable physicians or professionals who understand the service, but do not provide it. All participants in the group judgment process must be highly respected authorities in their fields. Ideally, they should be selected from individuals nominated by the key relevant specialty societies, although they must function as individuals, not as representatives of any group or interest.

Finally, for widespread acceptance by physicians, practice guidelines need to be sponsored, approved, and endorsed by a credible authority. In medicine this authority is vested in the key professional organizations: the American Medical Association, the American College of Physicians, the American College of Surgeons, and the specialty societies. Sponsorship by the government or by payers, such as the HCFA or insurance companies does not qualify. If physicians are to be convinced that the purpose of practice guidelines is to improve quality, not to cut costs, they must not come from payers, regulators, or the government.

Ultimately, practice guidelines should form the basis for review criteria and as the basis for payment. A major purpose of guidelines is to identify inappropriate indications for a service or procedure. No one believes that the government should pay for inappropriate care. But before guidelines are used for reimbursement they must be tested in clinical practice and found to be valid. This is an important principle, and one that has not been followed in the past. The medical profession has the duty and the responsibility to develop the standards of practice. Payment decisions should follow from these professional decisions, not the converse. In the past, we physicians have been slow to develop meaningful standards, in part because the methods were rudimentary. Now we have the methods to develop meaningful guidelines, and we have the will. The Congress, through the Agency, should welcome and support this commitment as the most effective way to improve the quality of health care for all Americans.

Chairman STARK. Thank you.

I apologize to the panel for being called away for some pork barrel duties that needed tending to. But I am aware of the testimony of Dr. Steinberg and Dr. Chassin, and I would like to ask a couple of general questions and maybe you each might comment.

This question has to do with the timetable. Whether we have priorities within which procedures—I mean, arguably, the Chair would be less interested in cosmetic surgery than other types of procedures that might be more urgent. And does the administration have priorities? Are we promoting the right agenda here? I did hear Dr. Leape suggest that we need $10 or $20 million. I assume that's more than is being spent now. It doesn't seem like very much more to me in something that could be this important.

I could not quite get Dr. Wilensky to ask for it this morning but maybe we can shove it at her and see if it won't happen. How are we doing on the timetable on our agenda? Could you each comment on that?

Dr. STEINBERG. Yes, sir, with regard to the priorities and the timetable—I think in Dr. Clinton's written testimony he identified a number of criteria that have been used in selection of the clinical disorders and the procedures that have been targeted by the PORT's, and I believe the Institute of Medicine was one entity that participated in the development of those priorities. I think those priorities are sound. They include such things as the frequency with which a particular type of patient is involved, or a procedure is performed; the cost, in aggregate, of performing those procedures, etc.

The one area which I have chosen to highlight, where I think more attention ought to be given, is in the area of emerging technologies. This is an area where the PORT's in some instances are addressing things such as laparoscopic cholecystectomy, as was mentioned. But I think it is an area where far too little attention is being given and I think that the number of new drugs, devices, and procedures that are coming down the pike, that are going to have substantial impact on the costs of care is quite staggering.

I know, for example, from a meeting at my hospital, Johns Hopkins Hospital, yesterday, that we anticipate an increase in our pharmacy budget for next year of from somewhere between $6 and $8 million, and that is due to three new drugs that are anticipated to be approved by the FDA. If you multiply that out on a national basis, it's a substantial amount of money.

Chairman STARK. Dr. Chassin.

Dr. CHASSIN. Yes, thank you.

I would make two points about priorities. In order to figure out the priority—and I will focus on guideline development, because I think the research effort is extremely valuable and will produce results, but in the long-term. The near-term results, I think, from the activities of the agency, will be felt with guideline development.

The prior question is what is the goal of practice guidelines? There may be several goals. If the goal is to improve quality, then one ideally would look across the range of what we do in medicine to try to find the burden of harm conveyed by various quality problems and try to prioritize those and go down the list and spend your money. That's not a process that will result in the develop-

ment of the most effective guidelines for another goal such as reducing costs. That goal would result in a different priority list. I think if one were to undertake that activity, you could fairly clearly and fairly quickly—not using research, but using expert opinion—come to some agreement on what the appropriate priority list for developing guidelines would be. I think that process needs to be undertaken.

I also think, though, that the process of developing guidelines needs to be accelerated. And far more resources need to be devoted to it than we currently have. Although I think the agency probably is making the most use of the resources that it has the private sector, I think, can be extremely helpful in developing guidelines as well. I will have to echo what Dr. Leape said though, that we have to be fairly careful about supporting processes that will produce high-quality guidelines.

Chairman STARK. Dr. Leape.

Dr. LEAPE. Thank you.

I think outcomes research is a very important and a huge job. It is appropriate that we be saying the amount of money we are, and probably expand that. But it is important to realize the results are going to be long in coming. In the meantime, with the use of practice guidelines, we can have an impact in a much shorter time frame. We could, in a matter of 3 to 5 years, produce 50 sets of guidelines which, if we targeted them towards the conditions that we have the most question about in terms of their inappropriate use, could significantly reduce inappropriate care.

We think it is not unreasonable to think that you could cut it by 25 to 50 percent, with a small number of guidelines done in a fairly short period of time. I should also point out that we will need guidelines to translate the results from the outcomes research. So the two go together, as the outcomes research gives us more information that needs to be incorporated into the guideline development process.

Chairman STARK. Thank you.

One last concern, and I, again, want to go across the table. I notice that Dr. Chassin's testimony indicates that you are using some practice guidelines now. Do the doctors like it? Do they resist—let me come back, let me finish my whole idea here. My popularity with organized medicine, who Dr. Leape suggests we need, is about where the President is with the Iraqis right now. They are kinder to me than the Iraqis would be to the President, but one of the things that somehow we get blamed for here is this administrative burden. I mean there is—and there is, indeed—there is a mishmash of paperwork and forms and bureaucracies to deal with. And I think I am sensitive to that.

I'm not so sure that organized medicine may not view some of this as just further impacting there. Also they have got to be used. I mean to do all of this and have the videotape sit on the shelf, or the book remain unopened, or the audiotape not played on the casette on the way to work, we have just begot a mouse and for a lot of screaming and high level work here.

So there is resistance to change, I suspect, in your profession, as in any profession. There is a concern that this could be something imposed upon people whom I think are, by nature, somewhat inde-

pendent and like their independence. They both accept it as a responsibility and as a quality in their life. So how are the ones you are using now working with regard to that? Is organized medicine really supportive or are they suspicious? And is this going to be something that will fit nto the physician's own image of how they like to practice medicine?

We will start with Dr. Leape, do you want to make a comment on that?

Dr. LEAPE. I would love to.

First of all, I think we really haven't tried the experiment. The kind of guidelines we're talking about have not really been in widespread use and not involuntary use. The use for payment purposes is a very different thing. If we're talking about physicians incorporating into their practice, then we really haven't had a chance to see how that works.

The most important aspect for a physician incorporating practice guidelines, in addition to the quality of the guidelines, is who they come from. And you mentioned your aversion to organized medicine, but unfortunately we can't live without them. Well, I merely say that if we want guidelines to have an impact, physicians have to believe in them, and the way they are going to believe in them is if they are endorsed by the leading societies. If the guidelines come from the American College of Physicians or the American College of Cardiology then the physicians have some confidence that they are properly done and that they are acceptable.

I would also add that doctors are concerned about inappropriate care. When we talk about guidelines now, people no longer say that's cookbook medicine. What they say is, yes, there's a problem out there and we want to do something about it. I think the climate has changed, and I think the climate is such that physicians will accept them and will use them if they are properly done.

Chairman STARK. Dr. Chassin.

Dr. CHASSIN. I think you are absolutely right to draw a tension between the administrative use of guidelines and their educational use. I think the guidelines should be used educationally. We should give physicians a chance to use them in that fashion. We should assist their use, however, because research has shown fairly clearly and consistently that there are ways to assist the educational implementation in ways that don't facilitate it, as I said in my testimony.

On the other hand, I also believe strongly from our own experience, that education isn't always going to work. We will always need another vehicle for the use of guidelines and in our situation we use it as part of preprocedure review. And even in that instance, we found that physicians, when they understand that these guidelines are clinically sophisticated, that they are produced in a scientific fashion, they much prefer to be judged on the basis of guidelines than to face administrative approaches that really offer no medical rationality at all and simply throw obstacles in the way of all sorts of care.

I would also like to point out that it's possible to implement guidelines in this fashion in a way that is sensitive to the administrative burden question. Our system, for example, can track physicians as to their appropriateness and exempt physicians from

review that practice appropriately. So it is possible, using some clinically sensitive approaches to minimize the administrative burden even in the implementation of guidelines in a payment system.

Chairman STARK. Dr. Steinberg.

Dr. STEINBERG. Thank you.

I don't have much to add to what has been said. I think that, for physicians to comply with them, it is absolutely critical that the guidelines be credible. Unless a guideline is based on a balanced and scientific evaluation of the underlying data, I don't think physicians will listen to it. I believe that, given the volume of guidelines that are being developed and the amount of information that physicians need in order to implement a guideline, I think that tools will need to be developed, computerized and otherwise, to facilitate physician compliance with guidelines with which they would actually like to comply.

Chairman STARK. Well, I want to thank the panel. As I say, this is fascinating to me and I hope that in some small way this committee and the bureaucratic apparatus of our Government can make a contribution. So often we are just in the bill-paying business, that it's kind of refreshing to see if we can't do something more positive than reducing fees for a change. I appreciate your interest and effort in this research and thank you, very much, for your contribution today.

Dr. LEAPE. Thank you.

Dr. CHASSIN. Thank you.

Dr. STEINBERG. Thank you.

Chairman STARK. I'm going to ask that the last two panels to join together and call the four remaining witnesses to the witness table together. That would bring Albert Mulley of the Mass General Hospital and Don Detmer, the vice president for health sciences at the University of Virginia; Paul Griner, representing the American College of Physicians; and John Seward, representing the American Medical Association.

I want to thank you all for being here. I don't know how you are seated at the table there, but why don't we start with Dr. Griner, and then we will go to Dr. Seward, Dr. Mulley, and Dr. Detmer.

Go ahead, Dr. Griner.

STRONG MEMORIAL HOSPITAL, ROCHESTER, NY; AND CHAIRMAN OF THE BOARD OF REGENTS, AMERICAN COLLEGE OF PHYSICIANS

Dr. GRINER. Thank you, Mr. Chairman.

The American College of Physicians is pleased to have this opportunity to present our views on the issue of medical practice guidelines in the context of overall reform of the health system. Our statement has been submitted and for the sake of time I will read selectively from it.

We wish to focus particularly on the issue of guidelines for medical practice, that is standards of care developed from the improved knowledge of the appropriateness and effectiveness of diagnostic and treatment strategies.

Our attempt today is to discuss guidelines in the context of systematic reform. We support the expansion of studies leading to improved practice guidelines but are concerned that a number of problems in the health care system, as we currently know it, will have to be addressed if guidelines are to be fully effective.

Six elements of the current system serve as obstacles to achieving value through the use of guidelines—the payment system, the manpower system, investment incentives, the liability system, utilization review, and for lack of a better term, the patient mindset.

First the payment system. We have long recognized that the current health care payment system promotes overutilization. When revenue is determined principally by the number of units of service provided the tendency is to do more, not less, particularly when malpractice concerns are added.

What chance do guidelines have in the face of this powerful economic incentive? Unless the financing system is changed from one that is driven by volume, to one that provides incentives for more discriminating and coordinated use of resources, guidelines that call for judicious use of a service or a procedure may be accepted only grudgingly and implemented slowly.

So we have to explore ways of closing the open-ended volume-driven nature of the payment system. We have to ask how we can determine an upper bound and then use our practice guidelines on research on effectiveness and outcomes to allocate resources across services, and providers, to maximize the effectiveness of our spending.

Second, the manpower system. There's abundant data showing that the number and mix of physicians has direct impact on the utilization of health services. A hands-off approach to physician manpower policy has resulted in excessive health services in some communities, while other communities have difficulty in providing primary care. The incentives are to super-specialize, to locate where the highest volume of services can be achieved, and to perform the most high-technology, high-cost procedures.

Guidelines which try to set appropriate levels of resource use, have limited chance of success in the face of these incentives in the manpower system. We must develop a manpower policy that utilizes the tools at our command and creates new ones, to begin to influence the number, mix, and distribution of physicians in accord with the Nation's needs.

Our existing tools include medical school class size, the number and distribution of residency training slots, and Government financing programs. The goals of manpower policy must be not only to reduce excessive use of high-cost services created by uncontrolled physician supply and distribution, but also to encourage minorities to enter medical professions, promote primary care, and enhance ambulatory care training, which to date falls far short of the reality that the hospital—as we traditionally know it—provides a smaller and smaller percentage of total medical care.

Third, our investment incentives. Our system has placed few controls on capital investment, particularly in the nonhospital setting. In the spirit of American free enterprise, we have opened up investment opportunities to anyone. The result has been the generation of excess capacity, particularly in the form of freestanding di-

agnostic and treatment centers. All are driven to maximize volume to realize profit on the investment.

We suggest that regulatory controls on capacity have some role to play in resolving this problem. It will be useful to study why earlier attempts to establish health planning mechanisms failed politically. Are we facing a different environment now in which receptivity to notions of regulating investments and setting other planning goals is enhanced?

Fourth, the liability system. I will skip through some of this in order to make sure I don't use up my time. The college urges this committee to consider, seriously, legislative reforms such as H.R. 1004, introduced by Representative Johnson and others. It is time to set national standards for tort reform to address a major national problem. These standards have been proven effective in California and elsewhere. This legislation also would encourage pilot tests of alternatives to the tort system, such as the administrative dispute resolution process proposed by a large group of medical organizations. Passage of legislation of this kind is a concrete step that Congress could take this year to begin reform of our health system.

It will take a major rethinking of old habits, to move away from defensive medical practices, but this is a necessary first step.

Fifth, utilization review. Utilization review must be restructured in order for guidelines to be effective. One could think of guidelines as the midpoint on a bell-shaped curve, in a sense, encompassing on each side of the guideline patterns of practice that are less resource intensive, as well as those that are more. Our current system sanctions physicians who are more resource intensive but provides no reward to those that are less.

As an alternative, practice patterns of physicians could be profiled to determine those who are outliers on the curve. The utilization review system then becomes an educational tool to bring the physician into the norm.

Sixth, the role of the patient has been largely overlooked in our efforts to achieve appropriate levels of resource use. For lack of any other direction, and supported by the media spotlight on medical miracles, the patient's mindset is one of trying anything and everything because it might work. We suggest that the role of the patient is a component of systemic change that must be considered as well. Attempts to implement guidelines are as dependent on changes in patient behavior as they are on the other reform elements we have discussed. Research on effectiveness and outcomes gives us for the first time an informed basis for bringing the patient into decisionmaking in the use of resources.

To conclude, Mr. Chairman, guidelines have been asked to help control costs, solve the liability problem, and in New York, serve in the credentialing process. We suggest that the appropriate function for guidelines is to achieve value by maintaining quality while optimizing the allocation of resources within a predictable level of spending.

We are asking a lot of science in its infant stages, but even as the science develops, we suggest that these efforts will fail without the overall restructuring we have outlined today.

Thank you.

[The prepared statement follows:]

STATEMENT OF THE AMERICAN COLLEGE OF PHYSICIANS BEFORE THE HOUSE WAYS AND MEANS COMMITTEE SUBCOMMITTEE ON HEALTH

April 30, 1991

Practice Guidelines in the Context of Health Care Reform

The American College of Physicians (ACP) is pleased to have this opportunity to present our views on the issue of medical practice guidelines in the context of overall reform of the health system. I am Paul F. Griner, MD, FACP, Chairman of the Board of Regents. I am General Director of Strong Memorial Hospital in Rochester, New York.

ACP is the nation's largest medical specialty society, representing more than 70,000 physicians practicing internal medicine and its subspecialties. One year ago, the College called for comprehensive reform of the health system. The breadth of the hearings being held this spring by the Ways and Means Committee and this Subcommittee indicates to us that you are considering reform across the system. We urge you to continue on that course, to think broadly and boldly about solutions not only to the critical, but relatively narrow, issue of access to care, but to the larger issues of the health care delivery and financing system. We hope that these hearings will be a landmark in the process of building the consensus necessary for Congress to act.

Practice guidelines can play an important role in this evolution, but only if the incentives of the overall system are consonant with their usage. Accordingly, our intent today is to discuss guidelines in the context of systemic reform.

Background

What accounts for the recent interest in the development of medical practice guidelines and research on the effectiveness and outcomes of medical care? At least three factors seem to be driving this trend towards a microeconomic approach.

First, the continuing escalation of health costs has prompted a search for new tools to control that growth.

Second, macroeconomic approaches to cost control - regulation, planning, and other efforts to control health care capacity - largely were dropped in favor of competition. But we submit that competition has not been effective in an environment that never had the essential characteristics of a marketplace.

Third, studies by Wennberg and others showed tremendous variations in medical practice for common medical problems, raising questions about the scientific basis for practice and suggesting a research agenda on the appropriateness and effectiveness of treatment options. Variation was seen to be the result of thousands of individual physician-patient decisions, so intervention would have to be at this level as well.

We do not believe that guidelines should be viewed as an approach to reduce costs. At best, what guidelines may promise is an improvement in the mix of services for the dollars spent, hopefully correcting problems of under- as well as over-utililization. This is not an insignificant contribution, because what we are talking about is maximizing value - that is, the quality of services for a given level of expenditures. If the widespread use of guidelines could help to assure the American public that it was getting value for its health care dollars, then this approach would have accomplished all we can reasonably ask of it.

But we would argue that this goal will not be achieved without the support of the macrosystem. The point we want to make in our statement today is that **system reforms must be put in place in order to facilitate desired change in medical practice.**

Development/Use of Guidelines

Before elaborating on the contention that guidelines will not be very effective without systemic reform, we should touch briefly on the development of guidelines themselves. We have testified previously to this Subcommittee and others, and to the Physician Payment Review Commission, about the College's Clinical Efficacy Assessment Project. This is the pioneering initiative, dating from the late 1970's, through which the College has developed practice guidelines for more than 150 clinical problems.

The essence of our project is to bring the best scientific information available to bear on the question of which interventions are appropriate and which are inappropriate or obsolete, under what circumstances they are appropriately utilized, and when they are unnecessary. Our studies give us a scientifically-derived benchmark on indications for use, that may in turn guide physicians' decisions on managing the particular clinical circumstances of individual patients.

The essential ingredients, if practitioners are to use these or other guidelines, are: good data, a credible source, and an accessible format. That is, physicians are likely to change their practices when they receive valid, scientifically-grounded information from a source that they trust (a professional organization, the medical literature, or a respected peer, as examples).

That information also must be provided in real time and in a usable fashion so that the physician can extract information on the many variables that need to be considered in managing an individual patient - not an easy task.

There is some evidence of a fourth factor that affects the use of guidelines, and that is implementation at the local level. We need to examine further the question of whether changes in practice patterns are most effectively realized when the application of practice guidelines is pursued at the hospital or community level.

These four elements that affect the use of guidelines are basically challenges to science and to the profession. We can and are rising to that challenge, spurred in good measure by the passage of payment reform legislation in 1989 and creation and funding of the Agency for Health Care Policy and Research.

Reforming the Health Care System

But the practice guidelines we develop will run up against the structure and incentives of our current delivery system. Our best efforts will be compromised, and the goal of achieving value for our expenditures will remain unmet, if we do not take on the task of health care reform. The remainder of our statement today addresses this issue.

Six elements of the current system serve as obstacles to achieving value through the use of guidelines: the payment system, the manpower system, investment incentives, the liability system, utilization review, and for lack of a better term, the patient "mindset".

Payment System: We have long recognized that the current health care payment system promotes overutilization. When revenue is determined principally by the number of units of service provided, the response is to provide more procedures and services than are necessary, particularly when malpractice concerns are added.

What chance do guidelines have in the face of this powerful economic incentive? Unless the financing system is changed from one that is driven by volume to one that provides incentives for more discriminating and coordinated use of resources, guidelines that call for judicious use of a service or procedure may be accepted only grudgingly and implemented slowly.

We have to explore ways of closing the open-ended, volume-driven nature of the payment system. We have to ask how we can determine an upper bound, and then use our

practice guidelines and research on effectiveness and outcomes to allocate resources across services and providers to maximize the effectiveness of our spending. In this way, guidelines are placed at the service of the payment system, and not at cross-purposes.

Manpower System: There is abundant data showing that the number and mix of physicians has direct impact on the utilization of health services. A hands-off approach to manpower policy has resulted in excessive health services in some communities, while other communities have difficulty in providing primary care.

Again, the incentives are to super-specialize, to locate where the highest volume of services can be achieved, and to perform the most high-tech, high-cost procedures. Again, guidelines which try to set appropriate levels of resource use have little chance of success in the face of these incentives of the manpower system.

We must develop a manpower policy that utilizes the tools at our command - and creates new ones - to begin to influence the mix and distribution of physicians in accord with the nation's needs. Our existing tools include medical school class size, the number and distribution of residency training slots, and government financing programs. The goals of manpower policy must be not only to reduce the excessive use of high-cost services created by uncontrolled physician supply/distribution, but also to encourage minorities to enter medical professions, promote primary care, and enhance ambulatory care training which to date falls far short of the reality that the hospital as we traditionally know it provides a smaller and smaller percentage of medical care.

Investment Incentives: Our system has placed few controls on capital investment, particularly in the non-hospital setting. In the spirit of American free enterprise, we have opened up investment opportunities to anyone. The result has been the generation of excess capacity, particularly in the form of freestanding diagnostic and treatment centers. All are driven to maximize volume in order to realize profit on the investment. With few constraints on who could be served, and a third-party payor ready to foot the bill, the opportunities for unnecessary services are greatly increased.

We suggest that regulatory controls on capacity have some role to play in resolving this problem. It will be useful to study why earlier attempts to establish health planning mechanisms failed politically. Are we facing a different enviroment now in which receptivity to notions of regulating investments and setting other planning goals is enhanced?

Liability System : Efforts to promote the use of guidelines on appropriate levels of service are likely to be undercut by our liability system. Defensive medicine is acknowledged to be a major concern, costing billions of dollars in unneeded tests and treatments. In the face of our litigious society, asking good clinicians to change practice patterns in accordance with guidelines, however scientifically valid they may be, may be asking them to risk exposure to a damaging lawsuit. Changes in the liability system will be necessary to make it more receptive to the appropriate use of guidelines.

The College urges this Subcommittee to consider seriously legislative reforms, such as HR 1004, introduced by Representative Johnson and others. It is time to set national standards for tort reform, to address a major national problem. These standards have been proven effective in California and elsewhere. This legislation also would encourage pilot tests of alternatives to the tort system, such as the administrative dispute resolution process proposed by a large group of medical organizations. Passage of this legislation is a concrete step that Congress could take this year to begin reform of our health system. It will take a major re-thinking of old habits to move away from defensive medical practices, but this is a necessary first step.

Utilization Review: A fifth element of our current system that presents an obstacle

to the use of guidelines is the way in which utilization review is conducted. Guidelines inserted into the current utilization review system would quickly be seen as another tool of the payors to control physicians. The reviewers have become the enemy, and guidelines would be seen as another weapon available to them. Obviously, the incentive in this process is not to comply with the guideline but, quite the contrary, to work to get around the guideline.

Utilization review must be restructured in order for guidelines to be effective. One could think of guidelines as the mid-point on a bell-shaped curve, in a sense encompassing, on each side of the guideline, patterns of practice that are less resource-intensive as well as those that are more resource-intensive. Our current system sanctions physicians who are more resource-intensive, but provides no rewards to those who are less resource-intensive. As an alternative, practice patterns of physicians could be profiled, to determine those who are outiers on the curve. The utilization review system then becomes an educational tool to bring the physician into the norm. With this kind of information on practice patterns, and the use of guidelines to set the norm, it should not be difficult to change physician behaviors. Evidence from the Maine Medical Assessment studies, for example, shows that physicians want to practice in the norm.

Role of the patient: The patient has largely been overlooked in our efforts to achieve appropriate levels of resource use. For lack of any other direction, and supported by the media spotlight on medical miracles and by doctors nervous about liability exposure, the patient's mindset is one of trying anything and everything because "it might work".

We suggest that the role of the patient is a component of systemic change that must be considered as well. Attempts to implement guidelines are as dependent on changes in patient behavior as they are on the other reforms we have discussed. Research on effectiveness and outcomes gives us, for the first time, an informed basis for bringing the patient into decision-making on the use of resources. We must explore means of helping patients apply their values to assess the possible outcomes and, with the physician, make decisions on treatment. We suggest that this is a critical component of moving from the excesses of a "try anything" system to a system in which thoughtful calculations are made on the value and costs of intervention.

The question is often heard of how we can achieve a consensus on the level of care and spending acceptable to our society. This kind of approach, where the patient is brought into decision-making and makes an informed judgment on possible outcomes, in light of his or her values, may provide the means for building that consensus.

Conclusion

Guidelines have been asked to help control costs, solve the liability problem and, in New York, serve in the credentialing process. We have suggested that the appropriate function for guidelines is to achieve value by maintaining quality while optimizing the allocation of resources within some level of spending.

Appropriately or not, we are asking a lot of a science in its infant stages. But even as the science develops, we suggest that these efforts will fail without the overall restructuring we have outlined today.

That is why, beginning with publication of an initial position paper exactly one year ago, the College has advocated systemic reform. We are now examining the components of the health system outlined today in order to develop policy options. We urge the Committee to think broadly and boldly beyond guidelines, beyond the critical but relatively narrow issue of access, to this kind of comprehensive reform.

Chairman STARK. Thank you, Dr. Griner.
Dr. Seward.

STATEMENT OF P. JOHN SEWARD, M.D., MEMBER, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION

Dr. SEWARD. Thank you, Mr. Chairman.

My name is P. John Seward. I am a family physician from Rockford, IL, and a member of the Board of Trustees of the American Medical Association. On behalf of the AMA I want to express our appreciation for this opportunity to appear before the subcommittee. Outcomes research has the potential for providing us with a method for identifying what works in medical care, to reduce inappropriate variation in the utilization of medical services, and to improve the quality and effectiveness of medical care.

We applaud the committee's interest in this important issue. The AMA also commends the current activities of both the Agency for Health Care Policy and Research and Health Care Financing for their efforts in this area. Organized medicine has assumed a leading role in outcomes research and welcomes expanded coordination with both public and private sector activities. We encourage the goals of such research to provide a better scientific basis for clinical management decisions and look forward to using the results of outcome research as foundations for the development and revision of practice parameters.

AHCPR and HCFA have made a concerted effort to work with the AMA and other physician organizations in this area. AMA stands ready to use our vast communication resources to disseminate this research to the profession once it has been appropriately developed. Outcomes research should be directed primarily toward education for patients and providers. Studies show that physicians are quick to respond to scientifically sound and clinically relevant information disseminated in a nonpunitive, educational process. Without appropriate practicing physician input however, the results of outcomes research projects are likely to be incorrect, clinically irrelevant, or have minimal impact.

The future expansion in the use of outcomes research cannot occur over night. The fact is that many of the components of outcomes research remain in the highly developmental phase as to data measurement, collection, and analysis.

Much remains to be learned about the most effective and prudent use of outcomes research findings. The AMA is well aware that concerns also exist regarding the delivery of inappropriate medical services. Only a carefully devised strategy for the collection and analysis of relevant data will target necessary areas for further research. The AMA is committed to working with AHCPR and HCFA to use the research effectively rather than seeking possible quick-fix solutions.

Another important issue also must be addressed, the subject of costs. We emphasize the need for further study before reaching inappropriate conclusions regarding the relative cost-effectiveness of one treatment over another. We must recognize that outcomes research will improve the quality and value of health care but may not in some cases act as a mechanism to effect short-term cost con-

tainment. By creating a prudent and deliberate research agenda guided by sound principles, long-term benefits will accrue from outcomes research activities.

The AMA and medicine have taken a lead role in the development of practice parameters. Today, over 30 physician organizations are developing practice parameters. Carefully developed practice parameters can increase the appropriateness of clinical care. For example, parameters developed by the American College of Cardiology and the American Heart Association have decreased the use of cardiac pacemakers by 25 percent in the Medicare population between 1984 and 1985.

And standards of inter-operative monitoring developed by the American Society of Anesthesiologists have reduced hypoxic injury in Massachusetts from an average of six injuries a year, to an average of one injury per year. These examples indicate that practice parameters can be very effective in improving the quality of medical care, as well as in the cost basis.

The recent establishment of the AMA specialty society practice parameters partnership and the practice parameters forum, provides an open and participatory process for representation of all of organized medicine in this process. We have also been engaged in a useful collaborative effort with the research community through the clinical appropriateness initiative in which the AMA, the Academic Medical Center Consortium, and the Rand Corp. are working with the medical specialty societies to facilitate development of appropriateness criteria and practice parameters.

In conclusion, the AMA supports outcomes research as an effective mechanism to improve the quality of medical care. We look forward to expanded cooperation with the Agency for Health Care Policy and Research, and the Health Care Financing Administration, and other quality improvement programs in this endeavor. The AMA truly appreciates the opportunity to appear before this committee, Mr. Chairman, and we will be pleased to respond to your questions, sir.

[The prepared statement follows:]

STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

to the
HEALTH SUBCOMMITTEE
of the
COMMITTEE ON WAYS AND MEANS
UNITED STATES HOUSE OF REPRESENTATIVES

Presented by

P. JOHN SEWARD, MD

RE: OUTCOMES EFFECTIVENESS RESEARCH

April 30, 1991

Mr. Chairman and Members of the Committee:

My name is P. John Seward, M.D. I am a family physician from Rockford, Illinois and a member of the Board of Trustees of the American Medical Association (AMA). On behalf of the AMA, I want to express our appreciation for this opportunity to appear before the Subcommittee to provide our views on the subject of outcomes effectiveness research.

Outcomes research has the potential to provide us with a method to identify what works in medical care, to reduce inappropriate variation in the utilization of medical services, and to improve the quality and effectiveness of medical care. We applaud the Committee's interest in this important issue.

CURRENT ACTIVITIES IN OUTCOMES RESEARCH

The AMA commends the current activities of both the Agency for Health Care Policy and Research (AHCPR), and the Health Care Financing Administration (HCFA) for their efforts in this area.

The AMA strongly supported the 1989 legislation creating the AHCPR as an agency to facilitate studies on outcomes of health care services and procedures. As stated in the authorizing legislation, the AHCPR is to:

> promote improvements in clinical practice and patient outcomes through more appropriate and effective health care services; promote improvement in the financing, organization, and delivery of health care services; and increase access to quality care.

The Agency funds various outcomes research projects, including the Patient Outcomes Research Team (PORT) projects, which are large-scale studies designed to identify and analyze the outcomes and costs of alternative practice patterns. Its research agenda provides a foundation to improve both quality of care and quality assurance programs. The Agency, even at this early stage, has shown great promise in identifying means to improve the quality of medical care. The AMA supports the budget request calling for $7 million in additional spending for the AHCPR. The kind of research being proposed and now being undertaken by AHCPR, and the widespread dissemination of the results of such research, will facilitate the profession's long-standing goals of improving the quality of medical care and assuring appropriate utilization.

The AMA also supports activities to initiate outcomes research by the Health Care Financing Administration (HCFA). Using data collected by HCFA's recently developed Uniform Clinical Data Set (UCDS), HCFA and the Peer Review Organizations plan to analyze patient outcomes. The AMA was pleased to accept HCFA's invitation to evaluate the components and proposed applications of this data base prior to the full implementation of the UCDS. Such participation by the medical profession is important,

as medical community involvement can and should work to reduce problems that have been seen in other programs that failed to include adequate physician involvement during the planning and testing phases. Involvement of the medical profession is vital to assure the necessary links for feedback to physicians regarding the findings and significance of the data. Organized medicine has assumed a leading role in outcomes research and welcomes expanded coordination with public and private sector activities. State medical societies and national medical specialty societies are participating in various outcomes research projects.

The medical profession encourages the goals of such research to provide a better scientific basis for clinical management decisions. We also look forward to using the results of outcomes research as the foundation for the development and revision of practice parameters. Practice parameters, in turn, can comprise a vehicle for disseminating outcomes research results to the physician community. The quality of patient care will be improved as both of these tools act in concert to assist physicians and patients in identifying appropriate treatment options.

Critical to the success of these efforts is the involvement of the medical profession in every phase of their development, evaluation and implementation. AHCPR and HCFA have made a concerted effort to work with the AMA and other physician organizations to assure that these important activities are designed with input from physician organizations and practicing physicians. We stand ready to use the vast communications resources of the AMA to disseminate this research to the profession once it is appropriately developed.

The Maine Medical Assessment Program, which was established in 1981, was an early attempt to study health care data. The Maine Program provides a model for appropriate data collection and feedback, achieving its success with the active involvement of the physician community. State medical societies in Vermont and Michigan also are actively involved in data evaluation and quality assessment projects. Medical specialty societies also play a key role. The American Academy of Orthopaedic Surgeons recently established a "Center on Outcomes Research," and held a symposium on musculoskeletal outcomes research in January 1991; and the American Urological Association is participating in an AHCPR outcomes research project.

The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), of which the AMA is a parent organization, is expanding its participation in outcomes assessment. The AMA endorses the JCAHO's Agenda for Change, that shifts the focus of hospital accreditation from assessing structural characteristics to evaluating outcomes. Our patients will be the beneficiaries of the fact that an increasing number of hospitals are using outcomes data as a basis for their quality assessment and quality improvement programs.

CURRENT AND FUTURE ISSUES IN OUTCOMES RESEARCH

The AMA continues to be a proponent of multidisciplinary research to assess the quality of health care. We believe such research should concentrate on patient outcomes relating to the structure and process of health care delivery and be broad enough in scope to be applicable to a multitude of health care settings. Research findings should then be used to evaluate and improve quality assurance programs. We also support continuing efforts in small area analysis and outcomes research, and adequate levels of governmental and private funding for outcomes research, practice parameters development and other approaches seeking to ensure substantial and appropriate physician input.

Outcomes research should be directed primarily towards education for patients and providers. Studies show that physicians are quick to respond to scientifically sound and clinically relevant information disseminated in a nonpunitive, educational process. Physicians organizations and practicing physicians must participate in the planning, development, testing, implementation, and interpretation of outcomes research. Without appropriate practicing physician input, the results of outcomes research projects are likely to be incorrect, clinically irrelevant or ignored.

With the expansion of outcomes research and its frequent reliance on computer analysis of claims data, it is imperative that patient and physician confidentiality be maintained. Stringent security procedures must be developed and strictly enforced to protect the use of data in all outcomes research projects.

The future expansion in the use of outcomes research cannot occur overnight. The fact is that many of the components of outcomes research remain in a highly developmental phase. What outcomes should be measured, and how relevant information should be collected, is still being analyzed. Moreover, much remains to be learned about the most effective and prudent uses of outcomes research findings.

The AMA is well aware that concerns also exist regarding the delivery of inappropriate medical services. Findings from a series of studies on the appropriateness of medical and surgical services provided in the late 1970s and early 1980s comprise the basis for these concerns. More recent data from Medicare Peer Review Organizations, however, suggest that the extent of inappropriate care may have been overstated. Incomplete scientific research in this area indeed led to the creation of AHCPR and current HCFA research efforts, and points to a need for the continuation of these current efforts. Only a carefully devised strategy for the collection and analysis of relevant data will target those areas for further research. The results of outcomes research can then be translated into the development of practice parameters which will serve to improve clinical practice. The AMA is committed to working with AHCPR and HCFA to use the research effectively, rather than seeking possible quick-fix solutions.

Another important issue also must be addressed, the subject of cost. The need to maximize the use of our resources is critical, and we recognize that cost factors may become an important consideration with respect to outcomes research. Nevertheless, we emphasize the need for conducting further research before reaching inappropriate conclusions regarding the relative cost effectiveness of one treatment over another. Inappropriate use of cost factors in this research could well lead to incorrect conclusions. We must recognize that outcomes research will improve the quality and value of health care, but may not, in some cases, act as a mechanism to effect short-term cost containment. By creating a prudent and deliberate research agenda, guided by sound principles, long-term benefits will accrue from outcomes research activities. Immediate short-term cost containment, however, should not be expected from such research.

Finally, the AMA believes that organizations that engage in outcomes research must:

- ensure the accuracy of the data used in outcomes research;
- include relevant physician organizations and practicing physicians in all phases of outcomes research, including the planning, development, implementation, and evaluation of outcomes research;
- provide physician organizations and practicing physicians with adequate opportunity to review and comment on interpretations of the results of outcomes research; and
- ensure that outcomes research is conducted in a manner that maintains patient and physician confidentiality.

AMA QUALITY INITIATIVES

The AMA and other physician organizations have taken a lead role in the development of practice parameters. Today, over thirty physician organizations are developing practice parameters.

The AMA's primary objective for practice parameters is to ensure that they are properly developed and implemented so that patients receive only appropriate, effective, and necessary medical care. To accomplish this goal, the AMA's efforts are being directed primarily toward working cooperatively with other physician organizations to facilitate their efforts to develop practice parameters.

Carefully developed practice parameters can increase the appropriateness of clinical care. For example:

- Guidelines on cardiac pacemakers, produced by the American College of Cardiology and the American Heart Association, have reduced uncertainty surrounding the appropriate use of cardiac pacemakers and have reduced the use of cardiac pacemakers by approximately 25% in the Medicare population between 1984 and 1988; and

- Standards on intra-operative monitoring developed by the American Society of Anesthesiology have reduced hypoxic injury in Massachusetts from an average of six injuries a year to an average of one injury per year.

These examples indicate that practice parameters can be very effective in improving the quality of medical care.

The most significant recent activity in encouraging the development of practice parameters is the establishment of the AMA/Specialty Society Practice Parameters Partnership and Practice Parameters Forum, which provides an open and participatory process for representation of all of organized medicine.

In addition to the activities of the Practice Parameters Partnership and Forum, the AMA has produced various products to encourage and facilitate further development of practice parameters by physician organizations. The AMA has published a Directory of Practice Parameters developed by national medical specialty societies and others. The Directory contains bibliographic information on over 1100 practice parameters. The AMA also published Attributes to Guide the Development of Practice Parameters. These documents have been well received by the medical profession as useful products to assist them in their development of practice parameters. The AMA also publishes, on a quarterly basis, Practice Parameters Update, which lists practice parameters under development, recently completed practice parameters, and practice parameters that have been withdrawn.

We have also been engaged in a useful collaborative effort with the research community through the Clinical Appropriateness Initiative in which the AMA, the Academic Medical Center Consortium and the RAND Corporation are working with the national medical specialty societies to facilitate development of appropriateness criteria and practice parameters. We have also identified a number of complex issues relating to the creation of clinical guidelines and practice parameters. These activities complement the work of AHCPR and HCFA. In our view, all of these projects represent positive advancements toward ensuring that the public receives appropriate and quality health care.

CONCLUSION

The AMA supports outcomes research as an effective mechanism to improve the quality of medical care. We recognize the important role of outcomes research in the development of practice parameters. We strongly urge, however, that the results of outcomes research be used in an educational manner and not as part of punitive mechanisms. Outcomes research must be conducted in a manner that protects the confidentiality of patients and physicians. Organizations which engage in outcomes research should be encouraged to actively involve the physician community. We look forward to expanded cooperation with AHCPR, HCFA, the JCAHO and other quality improvement programs in these endeavors. In this way, the accuracy and reliability of the data utilized in outcomes research can be ensured, and the proper integration of the research findings into the practice of medicine will occur.

The AMA appreciates the opportunity to appear before this Committee, and we will be pleased to respond to questioning.

5945p

Chairman STARK. Thank you, very much.
Dr. Mulley.

STATEMENT OF ALBERT G. MULLEY, JR., M.D., CHIEF OF GENERAL INTERNAL MEDICINE, MASSACHUSETTS GENERAL HOSPITAL, BOSTON, MA, AND ASSOCIATE PROFESSOR OF MEDICINE AND HEALTH POLICY, HARVARD MEDICAL SCHOOL

Dr. MULLEY. Thank you, Mr. Chairman.

In 1987 until the spring of last year, I served on a 17-member committee of the Institute of Medicine. As you know, that committee was mandated by Congress in the Omnibus Budget Reconciliation Act of 1986. That mandate reflected Congress' concern that the quality of health care was being adversely affected by the prospective payment system, and that the PRO's and other mechanisms for monitoring and maintaining quality of care, were inadequate.

The committee's charge was not only to examine the evidence regarding quality but also to design a strategy for quality review and assurance for Medicare in the future. I appreciate the opportunity to speak briefly about the committee's findings and recommendations. Other material has been submitted for the record.

First, let me briefly summarize our key findings about both the quality of care and about the current quality-assurance mechanisms and policies. We found the quality of care provided to Medicare beneficiaries to be generally good. Nevertheless, as we have heard, there is ample evidence that significant quality problems do exist. These include poor technical and interpersonal performance in the delivery of health services; overuse of services that may be inappropriate; and underuse of services that would likely be beneficial.

Despite substantial national investment in data collection and monitoring of care, current systems do not allow reliable estimates of the national burden of poor quality attributable to these different kinds of problems. We know the least about the burden of harm associated with underuse of needed services.

We found the current system of quality assurance to be largely ineffective and wasteful of resources. Vast amounts of time and effort on the part of the PRO's and other external monitors, and provider institutions in reaction, are expended to gather information about adherence to arbitrary standards that may have little to do with the quality of care.

The system has become increasingly burdensome to providers and increasingly intrusive in the doctor-patient relationship and decision making process. These burdens and intrusions would be justified if the process improved the professional knowledge base or provided benchmarks for quality improvement. But they appear to do neither.

Rather than recommend dismantling of the current PRO program, the committee advised a number of shifts in emphasis that would allow the available infrastructure to be redirected to more effective, efficient, and constructive use. First, the PRO program is currently inclined toward reaction, external inspection, and regulation. The future Medicare quality assurance program would be

more pro-active in data collection and feedback and would vigorously foster professionalism and internal quality improvement.

Such a shift would require the kind of improved availability of comparable clinical data from hospitals that is proposed in title III of the Health Equity and Access Reform Today Act of 1991.

Second, the present system heavily emphasizes providers and processes of care. The future program would give more attention to patient concerns and decision making and would adopt an aggressive outcomes orientation.

Third, PRO's rely heavily on monitoring information and on data collected for administrative purposes. The program recommended by the IOM would generate new knowledge from clinical practice, and thereby, improve clinical decision making rather than simply monitor it.

Fourth, although any quality assurance program must be concerned with individual providers, and specific incidents of care, the proposed program would place stronger emphasis on systems of care, on joint production of services by different providers, and on continuity of care.

Fifth, the new program would expand the focus of quality assurance activities beyond hospital in-patient care, to more fully include ambulatory office-based care, and care provided in other sites.

Sixth, a major deficiency of the present program is lack of evaluation and public oversight and a consequent inability to assess the benefit derived from Medicare resources devoted to the peer review program. The committee placed considerable emphasis on reform that would increase public accountability.

The IOM committee made 10 major recommendations. Two advised explicit expansion of the mission of the Medicare Program to be responsible and accountable for quality of care provided to the population of beneficiaries. A third recommendation focused on the needs for research in the areas of clinical evaluation such as quality of care, outcomes and effectiveness of alternative, preventive, and diagnostic and treatment strategies.

A fourth called for expanded capacity building and training of health professionals in the concepts and skills of quality assurance, and the kind of research that we have been talking about today, so that the funds could be used as efficiently as possible.

In the fifth recommendation, we called for a restructuring of the current program along the lines that I have just described. Two related recommendations address implementation of such a new effort. Finally, three recommendations were made regarding public oversight, accountability, and evaluation of the new program.

A common theme throughout the committee's deliberations was the need to foster, promote, and improve professionalism in health care. The committee fully recognized the limits of the professional model in achieving efficient and effective high quality health care. But we heard a great deal from beneficiaries about the importance of trust in the doctor-patient relationship.

We also heard a great deal from patients and doctors about the unintended negative impact on professionalism of those policies that have been designed with the best of intentions to achieve efficiency and assure quality in health care.

Taken as a whole, the committee's recommendations argue for an expansion of commitment to the health of the elderly and the development of systems to gather information about health care processes and outcomes that would be useful to all who are motivated to meet that commitment as efficiently and effectively as possible.

We believe that such an information system constitutes a public good, providing, if you will, a navigation system for the profession and for patients, and for those who bear the costs of care. Such an approach may be most likely to bring providers, patients, and policymakers to more clearly recognize their common interests in the quality of care.

I would be happy to answer any questions.

[The prepared statement follows:]

WRITTEN STATEMENT1
ON
THE INSTITUTE OF MEDICINE'S
REPORT ON
MEDICARE: A STRATEGY FOR QUALITY ASSURANCE

FOR THE HEARING ON
MEDICARE QUALITY OF CARE, AND OUTCOMES AND EFFECTIVENESS RESEARCH

THE SUBCOMMITTEE ON HEALTH,
THE COMMITTEE ON WAYS AND MEANS, U.S. HOUSE OF REPRESENTATIVES

April 30, 1991

BACKGROUND

At the quarter-century anniversary of the Medicare program, Congress and the nation can be justifiably proud of the accomplishments of the Medicare program in providing access to a generally high level of quality of care for the elderly. Near universal coverage by the Medicare program gives elderly people better access to health care than any other age group. Nevertheless, care is neither uniformly accessible nor uniformly good. Gaps in coverage and financial barriers exist and affect quality adversely. Excessive care, lack of needed care, and care of poor technical or interpersonal quality in hospital, office, and community settings continue to be reported.

Since nearly the beginning of the Medicare program, the federal government has tried to ensure that services reimbursed through the program are medically necessary, appropriate, and of a quality that meets professional standards. The two main efforts in this arena have been the Professional Standards Review Organizations (PSRO), in operation between 1972 and 1981, and now the Utilization and Quality Control Peer Review Organization (PRO) programs. The success of those programs in meeting those goals has been, at best, mixed.

In response to congressional concerns that quality of care was deteriorating under the prospective payment system (PPS) and that the PROs and other mechanisms for monitoring or maintaining quality were inadequate, the Omnibus Budget Reconciliation Act of 1986 directed the Department of Health and Human Services (DHHS) to request that the National Academy of Sciences "design a strategy for quality review and assurance in Medicare." In 1987, the Institute of Medicine (IOM) of the National Academy of Sciences appointed a distinguished committee to conduct the study, with funding from the Health Care Financing Administration.

In March 1990, the IOM released a two-volume report—*Medicare: A Strategy for Quality Assurance*—(available through the National Academy Press). Volume I contains the IOM committee's findings, conclusions, and recommendations for a comprehensive strategy to improve the quality of health care services delivered to the nation's Medicare population; Volume II compiles considerable information on quality measurement and assurance and records the study's many data collection and outreach activities.

In the early 1980s, disappointment at the limited effectiveness of the PSRO program prompted calls for its abolition or restructuring, and it was phased out as the PRO program was slowly put into place. Despite rhetorical emphasis on assuring quality of care, the new PRO program focused initially on use of services and costs, and the tie to the PPS was quite strong.

1Oral testimony was given by Albert G. Mulley, Jr., M.D., Chief of General Internal Medicine at Massachusetts General Hospital and Associate Professor of Medicine and of Health Policy at Harvard Medical School. Dr. Mulley served on the 17-member Committee of the Institute of Medicine which issued the report, Medicare: A Strategy for Quality Assurance, described in this statement.

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THE IOM REPORT

QUALITY DEFINITION

The IOM committee believed that a strategy for quality assurance (QA) must be guided by a definition of quality and an understanding of the burden of harm attributed to poor quality care. The IOM *defined quality of care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."* This definition emphasizes:

- health services, not just patient services or medical care;
- the care of populations, not just single episodes of care of patients;
- outcomes desired by patients, thus accentuating the role of informed patients in sharing in decisionmaking about their care; and
- professional competence and continuous professional growth for physicians and other clinical providers.

FINDINGS

The IOM contended that assessing quality of care requires understanding at least *three dimensions of quality*: *poor technical* or *interpersonal performance, overuse of unnecessary and inappropriate health services*, and *underuse of needed and appropriate services*. Current QA systems cannot provide reliable national estimates of the burden of poor quality attributable to these problems; for this reason they cannot answer congressional concerns about the effect of PPS or other financial or regulatory initiatives.

Despite significant reservations about the current PRO program, the IOM committee judged it to be sufficiently well-established that it should be improved and built on, not dismantled, in part because of the financial and psychological costs inherent in taking apart an existing program and creating a new one. Moreover, the existing program has useful procedures and organizational relationships, a cadre of committed and experienced professionals (physicians, nurse reviewers, and administrators), and better Medicare data sets and computer technology than were available previously.

SHIFT IN EMPHASIS

The IOM's proposed program for quality review and assurance aimed to shift the emphasis from current PRO directions or tasks to ones that reflected its vision of a quality assurance program (Table 1). First, the PRO program is inclined toward reaction, external inspection, and regulation; the future Medicare QA program would be more proactive in data collection and feedback and would vigorously foster professionalism and internal quality improvement. Such a shift would require the kind of improved availability of comparable clinical data from hospitals, that is proposed in Title III of the Health Equity and Access Reform Act of 1991. Second, the present system heavily emphasizes providers and the process of care; the future program would give more attention to patient and consumer concerns and decisionmaking and would adopt an aggressive outcomes orientation. Third, PROs rely heavily on monitoring information and on data collected for other purposes (such as billing) and do little constructive feedback to providers; the IOM program would generate new knowledge from clinical practice and return that information to providers in a timely way that improves clinical decisionmaking.

Fourth, although any QA program must be concerned with individual providers and specific incidents of care, the future program would place stronger emphasis on systems of care, on joint production of services by many different providers, and on continuity and episodes of care. Fifth, the Medicare peer review programs have traditionally focused on hospital inpatient care and have been able to do little or nothing with ambulatory, office-based care or care in other nonhospital settings; the program for the 1990s would make QA in all major settings a high priority. Sixth, a major deficiency of the present program is lack of evaluation and public oversight and a consequent inability to judge the benefit of Medicare resources devoted to the peer review program; the committee thus placed considerable emphasis on public accountability for its proposed program.

RECOMMENDATIONS

The IOM made ten major recommendations (Table 2). Two recommendations proposed *expanding the mission of the Medicare program to be responsible and accountable for quality of care--i.e., the health of the elderly* using the IOM's definition of quality of care. Such an expanded mission would aim:

- to improve the quality of health care for Medicare enrollees,
- to strengthen the ability of health care organizations and practitioners to assess and improve their own performance, and
- to identify and overcome system and policy barriers to achieving good quality of care.

The corollary to this--a comprehensive system of QA for Medicare--would include tools to help providers improve the health of the elderly and to help them monitor their own performance in behalf of Medicare beneficiaries. Therefore, a new program, like the one described in the IOM report, must concentrate on improving communication between doctors and patients and on broadening its concerns for the health and well-being of the elderly. Over the longer term, it might also be a prototype for QA systems to serve other parts of society as well.

In a third recommendation the IOM panel called for *rebuilding and restructuring the current PRO program into a Medicare Program to Assure Quality (MPAQ)*, with a redefinition of its functions to emphasize outcomes of care and feedback of clinically relevant information to health care providers. The MPAQ would use organizations like the PROs (renamed Medical Quality Review Organizations, or MQROs) as the basis for more systematic data collection, analysis, and feedback to providers and practitioners. In the committee's words, "the MPAQ would be explicitly oriented to quality of care, not to utilization or cost control," and it called for a 10-year implementation period that would include testing methods of quality assurance and time for building professional capacity to apply the new tools that are being developed. Two related recommendations dealt with *transition to the MPAQ*.

The MPAQ would plan and administer the quality assurance effort for Medicare. It would have three major responsibilities: (1) long- and short-term program planning for MQROs (e.g., to define the program guidelines for the MQROs, to review applications and make awards to MQROs, and to provide or arrange for technical assistance to MQROs); (2) monitor and evaluate MQRO operations and performance; and (3) aggregate, analyze, and report data on use of services, processes of care, and health status and outcomes of care.

MQROs would have several primary responsibilities: (1) obtain information on patient and population-based outcomes and practitioner and provider processes of care; (2) analyze these data, making appropriate adjustments for case mix, patient characteristics, and other pertinent information by various types of providers; (3) use these data to make judgments about practitioner or provider performance; (4) feed such information back to the internal QA programs of practitioners and providers (as well as report it to the MPAQ); and (5) carry out quality interventions and give technical assistance to internal, organization-based QA programs.

Three additional recommendations from the IOM committee concerned ***reliable public oversight, full accountability***, and ***rigorous evaluation of the impact of the new program***, including oversight of the MPAQ, partly through new advisory bodies.

Another recommendation focused on the needs for ***research*** in areas of clinical evaluation, such as quality of care, outcomes, and effectiveness, and on expanded ***capacity building and training*** for health professionals in the concepts and skills of quality assurance and research. The committee underscored the great importance of investing in the people, systems, and research needed to pursue the broad quality agenda set forth in its report. Finally, one recommendation called on Congress to authorize and appropriate funding adequate to support *all* the previous recommendations.

A common theme throughout Committee's deliberations was the need to foster, promote and improve professionalism in health care. The Committee fully recognized the limits of the professional model in achieving efficient and effective high quality health care. But we heard a great deal from beneficiaries about the importance of trust in the doctor-patient relationship. We also heard a great deal from patients and doctors about the unintended negative impact on professionalism of those policies that have been designed with the best of intentions to achieve efficiency and assure quality in health care. Taken as a whole, the Committee's recommendations argue for an expansion of commitment to the health of the elderly and the development of systems to gather information about health care processes and outcomes that would be useful to all who are motivated to meet that commitment as efficiently and effectively as possible. We believe that such an information system constitutes a public good, providing, if you will, a navigation system for the profession—and for patients and those who bear the costs of care. Such an approach may be most likely to bring providers, patients and policymakers to more clearly recognize their common interests in quality.

REACTIONS TO THE REPORT

A useful debate about the mission of the Medicare program and its QA effort is now under way. Policymakers and legislators are confronted with many difficult issues about how to maintain and improve the quality of health care for the elderly through a reformulated program that emphasizes outcomes and effectiveness of care, minimizes external inspection and regulation, encourages organization-based, professional quality assurance, and is accountable to the public. The IOM committee's findings and recommendations are widely regarded as a significant contribution to that debate, although no consensus on the proposed directions of the program has emerged since the report has been issued. The hearing of the Subcommittee on Health of the Committee on Ways and Means will be a constructive step toward better understanding and accord on appropriate directions in which to head.

Title III of the Health Equity and Access Reform Today Act of 1991 (H.R. 1565), "Preserving and Improving Quality of Care," calls for the Secretary of HHS to report to Congress recommendations regarding restructuring the Medicare peer review quality assurance program and for grants to conduct research on the applications of comprehensive information systems in improving patient care. These steps would be quite consistent with the thrust of the findings and recommendations in the IOM report.

TABLE 1 Shifts in Emphasis for a Quality Assurance Program for Medicare

Current Emphases	Future Emphases
Regulation Inspection External monitoring	Professionalism Improvement Internal programs
Provider and process orientation	Patient/consumer and outcomes orientation
Mostly nonclinical information with no feedback	Develop and use new knowledge from clinical practice and return information to providers to improve decision making
Individual providers and incidents of care	Systems of care and episodes of care
Hospital focus	Broader focus on all settings of care
Little public accountability or program evaluation	Greater public accountability and program evaluation

TABLE 2 Summary of the Recommendations for a Strategy for Quality Review and Assurance in Medicare

Recommendation no. 1. Congress should expand the mission of Medicare to include an explicit responsibility for assuring the quality of care for Medicare enrollees, where quality of care is defined as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

Recommendation no. 2. Congress should adopt the following three goals for the quality assurance activities of the Medicare program:
1. Continuously improve the quality of health care for Medicare enrollees, where quality is as defined in our first recommendation;
2. Strengthen the ability of health care organizations and practitioners to assess and improve their performance; and
3. Identify system and policy barriers to achieving quality of care and generate options to overcome such barriers.

Recommendation no. 3. Congress should restructure the Utilization and Quality Control Peer Review Organization (PRO) program, rename it the Medicare Program to Assure Quality (MPAQ), and redefine its functions.

Recommendation no. 4. Congress should establish a Quality Program Advisory Commission (QualPAC) to oversee activities of the Medicare Program to Assure Quality and to report to Congress on these activities.

Recommendation no. 5. Congress should establish within the Department of Health and Human Services a National Council on Medicare Quality Assurance to assist in the implementation, operation, and evaluation of the MPAQ.

Recommendation no. 6. Congress should direct the Secretary of the Department of Health and Human Services (DHHS) to report to Congress, no less frequently than every two years, on the quality of care for Medicare beneficiaries and on the effectiveness of MPAQ in meeting the goals outlined in Recommendation no. 2.

Recommendation no. 7. Congress should direct the Secretary of DHHS to initiate a program to make the Medicare Conditions of Participation consistent with and supportive of the overall federal quality assurance effort.

Recommendation no. 8. Congress should direct the Secretary of DHHS to support, expand, and improve research in and the knowledge base on efficacy, effectiveness, and outcomes of care and to support a systematic effort to develop clinical practice guidelines and standards of care.

Recommendation no. 9. Congress should direct the Secretary of DHHS to establish and fund educational activities designed to enhance the nation's capacity to improve the quality of care it receives.

Recommendation no. 10. Congress should authorize and appropriate such funds as needed to implement these recommendations.

Chairman STARK. Thank you, Dr. Mulley.
Dr. Detmer.

STATEMENT OF DON E. DETMER, M.D., PROFESSOR OF SURGERY AND VICE PRESIDENT FOR HEALTH SCIENCES, UNIVERSITY OF VIRGINIA, AND CHAIRMAN, COMMITTEE ON IMPROVING THE PATIENT RECORD, INSTITUTE OF MEDICINE

Dr. DETMER. Thank you, Mr. Chairman.

My name is Don Detmer, and I am professor of surgery and professor of business administration and vice president for health sciences at the University of Virginia, and chair of the Institute of Medicine's study committee on improving patient records.

This study committee examined the problems with existing medical records and proposes actions and research for their improvement in light of new technologies. In its just-released report, indeed this very day, the committee calls for health care professionals and organizations to adopt the computer-based patient record as the standard for all records used in patient care. I appreciate the opportunity to speak to you today about some of our major conclusions and recommendations.

The study is entitled "The Computer-Based Patient Record: An Essential Technology for Health Care." We believe that computer-based patient records, and computer-based patient record systems, are essential tools for health care that will help us to improve the quality of care, and at the same time, manage the costs of that care.

I would like carefully to define what I mean by a computer-based patient record, and explain why the IOM committee believes that computer-based records are essential to improving the effectiveness and efficiency of health care. The committee defined the CPR as an electronic patient record that resides in a system specifically designed to support users through the availability of complete and accurate patient data, practitioner reminders and alerts, clinical decision support systems, links to bodies of medical knowledge, and other aids to practitioners.

This definition encompasses a broader view of the patient record, moving from the notion of a location or device for keeping track of patient care events, to that of a resource with much enhanced utility in patient care, management of the health care system, and extension of knowledge.

The committee also emphasizes the critical role of the CPR user in capturing and effectively using the wealth of information that could be accessed through computerized patient records.

We believe that the computer-based patient record and these systems are essential to improving health care because they represent the first step toward meeting the information management challenges that are faced by health care practitioners, researchers, third party payors, policy makers, and patients. Without improved information management capabilities, it will be virtually impossible to create a longitudinal view of a patient's health experience, to coordinate health care services received from different health care providers, or to evaluate the value of health care services for an individual or population.

We also need a means for health care professionals to manage the everincreasing amount of medical knowledge for the benefit of patients and to meet the professionals' needs for life-long learning.

Shortrun benefits of computer-based patient records and CPR systems are likely to include: First, improved patient care resulting from increased availability of patient data, medical knowledge, and decision aids—for example, clinical alerts to keep you from ordering the right drug for the wrong person or vice versa; second, increased productivity of health care professionals from improved access to patient data when and where it's needed, and reduction of redundant data recording; and third, reduction in administrative costs, that is, production of routine reports, or submission of insurance claims.

Long-range benefits should include the ability to increase and improve medical knowledge, through research using patient data derived from CPR systems. That is, a better science base for clinical care can be expected to emerge.

Fortunately more powerful, affordable technologies to support computer-based patient records are now becoming available. And computers are increasingly accepted as a tool for enhancing efficiency in virtually all facets of everyday life. That is not to say, however, that CPR's are just around the corner. Significant work remains to be accomplished to reduce technological and nontechnological impediments to computer-based patient record development and implementation.

Research, development, and demonstration projects are needed in several key areas. Confidentiality and security measures need to be developed more fully. Data are needed on the costs and benefits of these systems. Standards are needed for data content and format. Data acquisition technologies do not yet meet the needs of computer-based records users.

Moreover, informational, organizational, and behavioral barriers to CPR development and implementation must be addressed. These include education needs for health care professionals on computer-based patient records, the cost of developing and acquiring these systems, lack of adequate networks for transmitting data, lack of leadership for resolving CPR issues and legal issues.

That notwithstanding, we believe that the time is ripe for a major CPR initiative. Given the support we have received for this study, both from the public and private sectors in terms of both time and money, there is evidence of much interest in improved patient records and information management. Other activities related to CPR provide a sense of momentum that is building—in the public sector, related activities included GAO report on automated medical records; the work of AHCPR in improving data bases for research and developing clinical practice guidelines; HCFA's efforts in developing uniform clinical data sets; the National Library of Medicine's progress on uniform medical language systems, as well as efforts in the Departments of Defense and the Veterans Affairs.

Within the private sector, health care provider institutions and computer vendors are grappling with the issue, and several have made progress. The American Medical Association and other organizations, as you heard, are playing a major role in the develop-

ment of clinical practice guidelines which relate to the CPR and quality improvement.

The challenge we face in developing and implementing CPR systems that are affordable and acceptable to practitioners should not be under-estimated. Time, money, leadership, and coordination are needed. The committee believes that a public-private partnership is critical for success. Each sector has important contributions to make. Representatives from both sectors must be involved and resources must come from both sectors. In addition, enthusiastic involvement of the practice community of medicine and other health professions is a requirement for success.

In its recommendations, the committee has outlined a strategic plan for achieving widespread CPR implementation. The committee sought to create a mechanism that will foster innovation, collaboration, and prudent resource allocation through its recommendation to create the Computer-Based Patient Record Institute. The committee's other recommendations focus on specific impediments, needed research and development, promulgation of standards, etc.

We are pleased to see Congress giving attention to this important issue in the form of title III, Preserving and Improving the Quality of Care; of H.R. 1565, the Health Equity and Access Reform Today Act of 1991.

On behalf of the Institute of Medicine Committee on Improving Patient Records, I would like to thank you again for the opportunity to share our views and recommendations.

I have included the executive summary from our report as a part of my written testimony, and would be happy to answer any questions.

[The prepared statement follows:]

WRITTEN STATEMENT OF DR. DON E. DETMER[1] ON
THE INSTITUTE OF MEDICINE REPORT
COMPUTER-BASED PATIENT RECORDS: AN ESSENTIAL TECHNOLOGY FOR HEALTH CARE

FOR THE HEARING ON
MEDICARE QUALITY OF CARE, AND OUTCOMES AND EFFECTIVENESS RESEARCH

THE SUBCOMMITTEE ON HEALTH
THE COMMITTEE ON WAYS AND MEANS, U.S. HOUSE OF REPRESENTATIVES

APRIL 30, 1991

The Institute of Medicine Committee on Improving the Patient Record has just released its report, "Computer-based Patient Records: An Essential Technology for Health Care." This study committee examined the problems with existing medical records and proposes actions and research for their improvement in light of new technologies. In its report, the committee calls for health care professionals and organizations to adopt the computer-based patient record as the standard for all records used in patient care.

The committee believes that computer-based patient records (CPRs) and computer-based patient record systems are essential tools for health care that will help health care professionals improve the quality of care and at the same time manage the costs of that care. The committee defined the CPR as an electronic patient record that resides in a system specifically designed to support users through the availability of complete and accurate patient data, practitioner reminders and alerts, clinical decision support systems, links to bodies of medical knowledge, and other aids to practitioners. This definition encompasses a broader view of the patient record--moving from the notion of a location or device for keeping track of patient care events to that of a resource with much enhanced utility in patient care, management of the health care system, and extension of knowledge. The committee also emphasized the critical role of the CPR user in capturing and effectively using the wealth of information that could be accessed through CPRs.

The committee believes that CPRs are essential to improving health care because they represent the first step toward meeting the information management challenges that are faced by health care practitioners, researchers, third-party payers, policymakers, and patients. Without improved information management capabilities it will be virtually impossible to create a longitudinal view of a patient's health experience, to coordinate health care services received from different health care providers, or to evaluate the value of health care services for an individual or a population. We also need a means for health care professionals to manage the ever-increasing amount of medical knowledge for the benefit of patients and to meet the professionals' needs for life-long learning.

Short-run benefits of CPRs and CPR systems should are likely to include:

1. improved patient care resulting from increased availability of patient data, medical knowledge, and decision aids;
2. increased productivity of health care professionals from improved access to patient data when and where needed and reduction of redundant data recording; and
3. reduction in administrative costs (e.g., production of routine reports or submission of insurance claims).

Long-run benefits should include the ability to increase and improve medical knowledge through research using patient data derived from CPR systems.

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[1]Don E. Detmer, M.D., is Professor of Surgery and Vice President for Health Sciences at the University of Virginia, Charlottesville. Dr. Detmer is chair of the Institute of Medicine Committee on Improving the Patient Record which issued the report, "Computer-based Patient Records: An Essential Technology for Health Care", described in this statement.

Fortunately, more powerful, affordable technologies to support computer-based patient records are now becoming available and computers are increasingly accepted as a tool for enhancing efficiency in virtually all facets of everyday life. That is not to say, however, that CPRs are just around the corner. Significant work remains to be accomplished to reduce technological and nontechnological impediments to CPR development and implementation. Research, development, and demonstration projects are needed in several key areas. Confidentiality and security measures need to be developed more fully. Data are needed on the costs and benefits of CPR systems. Standards are needed for data content and format. Data acquisition technologies do not yet meet the needs of CPR users. Moreover, informational, organizational, and behavioral barriers to CPR development and implementation must be addressed. These include: education needs for health care professionals on CPRs, the costs of developing and acquiring CPR systems, lack of adequate networks for transmitting data, lack of leadership for resolving CPR issues, and legal issues.

The committee believes that the time is right for a major CPR initiative. Given the support that was provided to this study from both the public and private sectors--in terms of both time and money--there is evidence of much interest in improved patient records and information management. Other activities related to CPRs provide a sense of the momentum that is building. In the public sector, related activities include the GAO report on automated medical records, the work of AHCPR on improving databases for research and developing clinical practice guidelines, HCFA's efforts in developing the uniform clinical data set, NLM's progress on the Unified Medical Language System, and the efforts of the Departments of Defense and Veterans Affairs in developing comprehensive medical information systems. Within the private sector, health care provider institutions and computer vendors are grappling with this issue and several have already made progress toward automated patient records. The American Medical Association and other professional organizations are playing a major role in the development of clinical practice guidelines--which relate to the CPR and quality enhancement.

The challenge we face in developing and implementing CPR systems that are affordable and acceptable to practitioners should not be underestimated. Time, money, leadership, and coordination are needed. The committee believes that a public-private partnership is critical for success. Each sector has important contributions to make. Representatives from both sectors must be involved and resources must come from both sectors. In addition, enthusiastic involvement of the practice community of medicine and other health professions is a requirement for success.

Through its recommendations, the committee has outlined a strategic plan for achieving widespread CPR implementation. The committee sought to create a mechanism that will foster innovation, collaboration, and prudent resource allocation through its recommendation to create the Computer-based Patient Record Institute. The committee's other recommendations focus on specific impediments: needed research and development, promulgation of standards for CPR data and security, review of legal constraints and remedies, distribution of costs for CPR systems, and education of health care professionals.

The committee is pleased to see Congress giving attention to this important issue in the form of Title III, Preserving and Improving Quality of Care, of H.R. 1565 (Health Equity and Access Reform Today Act of 1991).

The executive summary of the committee's report follows.

EXECUTIVE SUMMARY
COMPUTER-BASED PATIENT RECORDS: AN ESSENTIAL TECHNOLOGY FOR HEALTH CARE

The patient record touches, in some way, virtually everyone associated with providing, receiving, or reimbursing health care services. This wide range of application and use has led to efforts to automate the collection, storage, and management of the data that constitute these records. But in spite of more than 30 years of exploratory work and millions of dollars in research and implementation of computer systems in health care provider institutions, patient records today are still predominantly paper records. This evident lack of diffusion of information management technologies in the health care sector has limited the tools available for effective decision making from the bedside all the way to the formulation of national health care policy. Given the importance of patient data to the activities of all portions of the health care spectrum, the Institute of Medicine (IOM) undertook a study to improve patient records, acting in response to expanding demands for information and for increased functional capacity of patient record systems, as well as the considerable recent technological advances that bring the benefits of computer-based patient records within reach.

As its first step, the IOM study committee examined why previous work had not resulted in widespread improvement of patient records and asked whether and how another effort might be successful. The committee identified five conditions in the current health care environment that increase the likelihood of success.

1. The uses of and legitimate demands for patient data are growing. Part of this growth can be attributed to increased concern about the content and value of clinical therapies and a recent intense focus on health services research.
2. More powerful, affordable technologies to support computer-based patient records are now available.
3. Increasingly, computers are being accepted as a tool for enhancing efficiency in virtually all facets of everyday life.
4. Demographic factors such as an aging population (which results in a growth in chronic diseases) and the continued mobility of Americans create greater pressures for patient records that can manage large amounts of information and are easily transferable among health care providers.
5. Pressures for reform in health care are growing, and automation of patient records is crucial to achievement of such reform.

The combination of these factors led the committee to conclude that computerization can help to improve patient records, and improved patient records and information management of health care data are essential elements of the infrastructure of the nation's health care system.

USER NEEDS AND SYSTEM REQUIREMENTS

The patient record of the future will have many more users and uses than it has at present. Direct providers of care (physicians, nurses, dentists, and other health care professionals) will remain the users of highest priority in design considerations. However, with the expanded functions projected for patient records (e.g., their use in supplying data for research or for insurance claims), the range of users considered in record system design will widen. The needs of all users will be met to an extent not possible in current record systems. Ultimately, of course, the most significant beneficiary of improved patient records should be the patient.

The committee identified five objectives for future patient record systems. First, future patient records should support patient care and improve its quality. Second, they should enhance the productivity of health care professionals and reduce the administrative costs associated with health care delivery and financing. Third, they should support clinical and health services research. Fourth, they should be able to accommodate future developments in

bealth care technology, policy, management, and finance. Fifth, they must have mechanisms in place to ensure patient data confidentiality at all times.

To achieve these objectives, future patient records must be computer based. However, merely automating the form, content, and procedures of current patient records will perpetuate their deficiencies and will be insufficient to meet emerging user needs. The committee defined the computer-based patient record as an electronic patient record that resides in a system specifically designed to support users through availability of complete and accurate data, practitioner reminders and alerts, clinical decision support systems, links to bodies of medical knowledge, and other aids. This definition encompasses a broader view of the patient record than is current today, moving from the notion of a location or device for keeping track of patient care events to a resource with much enhanced utility in patient care (including tbe ability to provide an accurate longitudinal account of care), in management of the bealth care system, and in extension of knowledge.

In the past, a patient record has served the basic function of storing patient data for retrieval by users involved with providing patient care. Even this classic function must be broader in the future, however, especially with respect to the key feature of flexibility. Different health care professionals will require different modes of record information retrieval and display. Today, both paper and computer records are often cumbersome tools for tbese tasks. The record of the future must be far more flexible, allowing its users to design and utilize reporting formats tailored to their own special needs and to organize and display data in various ways.

The patient record system of the future must provide other capabilities as well, including links to administrative, bibliographic, clinical knowledge, and research databases. To meet the needs of clinicians, CPR systems must be linked to decision support systems; they must also support video or picture graphics and must provide electronic mail capability witbin and between provider settings.

Future CPR systems must offer enhanced communications capabilities to meet emerging user needs. The systems must be able to transmit detailed records reliably across substantial distances. Physician offices must be able to communicate with local hospitals and national bibliographic resources. In hospitals, all of the various departmental systems (e.g., finance, laboratory, nursing, radiology) must be able to communicate with the patient record system. In the larger health care environment, computer-based information management systems must be able to communicate with providers, third-party payers, and other health care entities, while at all times maintaining confidentiality of tbe information.

If users are to derive maximum benefits from future patient record systems, they must fulfill four conditions. First, users must have confidence in the data--which implies that the individual who collects data must be able to enter them directly into the system and that the system must be able to reliably integrate data from all sources and accurately retrieve them whenever necessary. Second, they must use the record actively in the clinical process. Third, they must understand that the record is a resource for use beyond direct patient care--for example, to study the effectiveness and efficiency of clinical processes, procedures, and technologies. Fourth, tbey must be proficient in the use of future computer-based record systems (i.e., the systems described in this report) and the tools that such systems provide (e.g., links to bibliographic databases or clinical decision support systems).

COMPUTER-BASED PATIENT RECORD TECHNOLOGIES

Over the past decades, progress has been steady toward developing complete CPR systems, and several powerful clinical information systems have become operational in recent years. Typically, development on these systems began at least a decade ago, and some have been under development for more than two decades. No current system, however, is capable of supporting the complete CPR.

Those clinical information systems that most closely approximate the CPR system envisioned by the committee share several common traits. First, they maintain a large data dictionary to define the contents of their internal CPRs. Second, all patient data recorded in

the CPR are tagged with the time and date of the transaction, thus making the CPR a continuous chronological history of the patient's medical care. Third, the systems retrieve and report data in the CPR in a flexible manner. Finally, the systems offer a research tool for using the CPR data.

Most of the technological barriers that formerly impeded development of CPR systems have either disappeared already or are about to dissolve. Nevertheless, although no technological breakthroughs are needed to realize CPR systems, further maturation of a few emerging technologies, such as hand-held computers, voice-input or voice-recognition systems, and text-processing systems may be necessary to develop state-of-the-art CPR systems in the 1990s. In some cases, promising technologies must be tested further in "real-life" situations; in other cases, technologies that have proved beneficial in applications in other fields must be adopted for use in health care.

In addition to further development of necessary technologies, a variety of standards must be developed, tested, and implemented before the CPR can realize its full potential at both the macro (e.g., epidemiological) and micro (e.g., physician office) levels. Standards to facilitate the exchange of health care data are needed so that clinical data may be transmitted on networks or aggregated and analyzed to support improved decision making. Standards are also needed for the development of more secure CPR systems. This effort should focus on ensuring the integrity of the clinical data in the CPR and protecting its confidentiality. It is crucial that confidentiality be maintained in CPR systems not only for the patient but also for health care professionals.

NONTECHNOLOGICAL BARRIERS

In addition to technological advances, successful implementation of CPR systems requires elimination of the barriers to development (i.e., the production of new capabilities) and diffusion. It also requires that the concerns of many interested parties be addressed and that individuals and organizations with resources to support needed changes be engaged in the effort.

Many impediments to the CPR and to CPR systems arise from a lack of awareness and understanding of their capabilities and benefits. The intellectual understanding of what needs to be done, how to do it, and for whom to do it--that is, the demanding collection of insights required for design--is a continuing problem that must be addressed. (For example, when users are asked what capabilities they would like to have available to them, they may have difficulty imagining what CPR systems will be able to do in the future.) System purchasers and users often lack adequate information about the benefits and costs of the CPR. Developers and vendors require more specific information about what users want from systems and what price providers would be willing to pay for systems that meet their needs. Activities aimed at improving and disseminating available information about CPR systems--for instance, through demonstration projects and education programs--constitute an important step toward CPR implementation.

Other impediments arise from the lack of an infrastructure to support CPR development and diffusion. Needed infrastructure components are standards for communication of data (i.e., vocabulary control and data format standards); laws and regulations that protect patient privacy but do not inhibit transfer of information to legitimate users of data outside the clinical setting; experts trained in the development and use of CPR systems; institutional, local, regional, and national networks for transmitting CPR data; reimbursement mechanisms that pay for the costs of producing improved patient care information; and a management structure (i.e., an organization) for setting priorities, garnering and allocating resources, and coordinating activities.

Consideration of the various barriers to CPR development, the interest and resources of individuals and organizations able to effect change, and the concerns of individuals who would be affected by implementation of CPRs prompted the committee to identify eight critical activities that will help advance CPR development: (1) identification and understanding of CPR design requirements; (2) standards development; (3) CPR and CPR systems research and development; (4) demonstrations of effectiveness, costs, and benefits of CPR systems; (5) reduction of legal constraints for CPR uses as well as enhancement of legal protection for patients; (6) coordination of resources and support for CPR development and diffusion; (7)

coordination of information and resources for secondary patient record databases; and (8) education and training of developers and users.

Accomplishing these activities will require adequate funding and effective organization. The committee reviewed organizational structures that could provide the necessary framework for coordinating CPR activities and concluded that no existing organization has the mandate and resources necessary to lead the CPR effort. Thus, for reasons set forth more fully in Chapter 4, the committee believes that a new organization is needed to support CPR development and implementation. The committee has proposed a framework for the establishment of such an organization, but it also emphasizes that achieving adequate resources for and engaging the appropriate parties in CPR development efforts are more important than the precise structure of the recommended organization.

RECOMMENDATIONS

The committee believes its recommendations (see Table 1) effectively address the potential barriers to routine CPR use. The first recommendation defines CPRs and CPR systems as the standard for future patient records; the second proposes an organizational framework within which barriers to CPR implementation can be systematically addressed and overcome. The remaining recommendations focus on specific impediments: needed research and development, promulgation of standards for CPR data and security, review of legal constraints and remedies, distribution of costs for CPR systems, and education of health care professionals.

The committee believes that the CPR can play an increasingly important role in the health care environment. This role begins in the care process as the CPR provides patient information when needed and supports clinical decision making. It extends to management of care through the establishment of a mechanism by which quality assurance procedures and clinical practice guidelines are accessible to health care professionals at the time and site of patient care. It also includes opportunities for reducing administrative costs and frustrations associated with health care financing and for capturing administrative data for internal and external review. Finally, the CPR's role extends to capturing relevant, accurate data necessary for provider and consumer education, technology assessment, health services research, and related work concerning the appropriateness, effectiveness, and outcomes of care.

The committee recognizes the considerable amount of work that remains to be done and the practical limitations that must be overcome before CPRs become the standard mode of documenting and communicating patient information and before they are perceived and used as a vital resource for improving patient care. The challenge of coordinating CPR development efforts in the pluralistic health care environment is great. Resources are limited and must be used wisely.

The committee is convinced that proper coordination and appropriate resources will lead to achievement of the goal of widespread CPR utilization within a decade. The desire to improve the quality of and access to patient data is shared by patients, practitioners, administrators, third-party payers, researchers, and policymakers throughout the nation. CPRs and CPR systems can respond to health care's need for a "central nervous system" to manage the complexities of modern medicine--from patient care to public health to health care policy. In short, the CPR is an essential technology for health care today and in the future.

Table 1 Summary of the Recommendations of the Institute of Medicine Committee on Improving the Patient Record

1. The committee recommends that health care professionals and organizations adopt the computer-based patient record (CPR) as the standard for medical and all other records related to patient care.

2. To accomplish Recommendation No. 1, the committee recommends that the public and private sectors join in establishing a Computer-based Patient Record Institute (CPRI) to promote and facilitate development, implementation, and dissemination of the CPR.

3. The committee recommends that both the public and private sectors expand support for the CPR and CPR system implementation through research, development, and demonstration projects. Specifically, the committee recommends that Congress authorize and appropriate funds to implement the research and development agenda outlined herein. The committee further recommends that private foundations and vendors fund programs that support and facilitate this research and development agenda.

4. The committee recommends that the CPRI promulgate uniform national standards for data and security to facilitate implementation of the CPR and its secondary databases.

5. The committee recommends that the CPRI review federal and state laws and regulations for the purpose of proposing and promulgating model legislation and regulations to facilitate the implementation and dissemination of the CPR and its secondary databases and to streamline the CPR and CPR systems.

6. The committee recommends that the costs of CPR systems be shared by those who benefit from the value of the CPR. Specifically, the full costs of implementing and operating CPRs and CPR systems should be factored into reimbursement levels or payment schedules of both public and private sector third-party payers. In addition, users of secondary databases should support the costs of creating such databases.

7. The committee recommends that health care professional schools and organizations enhance educational programs for students and practitioners in the use of computers, CPRs, and CPR systems for patient care, education, and research.

Chairman STARK. Thank you, very much.

Dr. Detmer, in the automated or electronic filing of these records, are the physicians going to see that as more of an intrusion on their practice, or is that going to lessen the hassle factor? Being sensitive to that, I can see somebody who doesn't like to fill out charts now, saying "Oh, my goodness, now I have got to learn DOS or Mac or something." How is the physician community going to react to this?

Dr. DETMER. I think what will happen, to some extent, Mr. Chairman, is a function of age. Increasingly our students at this point are coming in already computer literate, that's a fact. There's a spectrum of interest, candidly. In fact, a lot of places now do have fairly sophisticated hospital information systems and a number of clinicians are using these with a great deal of facility and interest.

I met with the Scientific Affairs Council of the AMA this weekend and found them actually to be at least at the surface of it quite interested and supportive of CPR's. Basically I think we physicians see that these things are inevitable. I think the more important thing is that can we, as a group of clinicians, get involved with it early enough and help shape the direction it goes.

Chairman STARK. Are you aware of hospitals using this system now?

Dr. DETMER. Well, I would say current systems today probably have, at most, half of the features that we really are talking about in terms of what could be achieved by the turn of the century. So that nobody today really has the final word on this. This is a research and development effort, but we really think that models, mature models can be available fairly soon.

Chairman STARK. I'm thinking, particularly in a parochial sense, of Kaiser in my own district. We have one-half of a million people. Not only do they have the hospital records, but the medical records, and I'm not sure they are computerized. I think they have huge filing rooms that boggle the mind. They may be working toward that.

Dr. DETMER. Dr. Collen was head of one of our subcommittees that set up their automated screening system at Kaiser. So, in fact, he played quite a role in this study.

Chairman STARK. Thank you.

Dr. Mulley, you have recommended amending our Medicare's hospital conditions of participation. Can you be a little more specific on that, and are there standards for other providers?

Dr. MULLEY. Are there standards for other providers?

Chairman STARK. Yes, I once suggested periodic reviews for physician certification specialties. It was not something that was unanimously adopted, I might add.

Dr. MULLEY. Well, there was the general sense in our committee that policy was too wedded to standards, asking people to adhere to standards—and externally monitoring their adherence to standards—as opposed to giving people incentives to participate in systems that allowed them to recognize how they measured up to their peers, whether we are talking about individual providers or peer institutions, if we are talking about institutional providers.

There was a general recommendation for movement away from emphasis on standards and a movement towards for instance, ac-

creditation for participation in systems that create new knowledge for the entire collective body of the profession and also that let individual provider or individual institution know where they sit on the quality distribution. And, again, quality would be defined with a heavy emphasis on the outcomes that are important to patients, again, increasing the credibility of this system to the profession.

Chairman STARK. Thank you.

Dr. Griner and Dr. Seward, I sense you have somewhat different approaches to the problem, but Dr. Griner, you, in particular, are basically suggesting expenditure caps. You are suggesting something we have never been involved in, although indirectly on manpower practices there. I think, in other committees, people have talked about more encouragement or financial assistance for training in the primary care specialties and are cutting back, say on the more expensive graduate medical education for the specialties as a way to fine tune that.

I have never liked the idea of this committee getting into that area. I have never figured out why we have graduate medical education tacked on to Medicare anyway. I mean I have no quarrel with it, but it just doesn't seem to normally fit into a system that pays for medical care for seniors. But as long as we have it, it won't go away.

Do you see the outcomes research or this type of study being useful in determining how many specialists we need, and ought we to be fussing with that? I want to start with that. You are really suggesting that we ought to have caps and that this would then be useful under the caps.

I would like Dr. Seward's comment on that, as well.

Dr. GRINER. Mr. Chairman, we are dealing with issues here of access, of quality, and of cost. Our position, speaking now for the American College of Physicians, whether having to do with the effective implementation of guidelines, or other elements that bear on those three important goals, it is our position that fundamental attention to reform of the health care system is going to be needed in order to achieve those objectives. We certainly promote, support, and feel positive generally about the applications of guidelines and the logic behind them.

We are concerned whether it has to do with guidelines bearing on quality, or whether it has to do with issues of cost containment, or whether it has to do with access that our objectives will be constrained if we fail to step back and look fundamentally at the elements of the system that need to be changed. That's the reason for the focus on my comments this morning.

Chairman STARK. Dr. Seward.

Dr. SEWARD. Thank you, Mr. Chairman.

The AMA, I think, feels very strongly that the concept of practice guidelines finally will—and practice parameters—will lead us into a way of truly assessing and being able to make sure that my patient understands what quality is, that it is reproducible.

I am reminded of a statement that Chairman Rostenkowski said last week that I think really kind of hit me when he was talking about how you folks had raised taxes and you heard about it, and everybody complained about it until December. Then all of a sudden when you gave good service, and good products, we haven't

heard the complaints. That truly kind of hit me, and I think I looked to myself in that same regard as saying, if I can tell my patients that they have good—good service—and I can show them good service, that will be hopefully cost effective too.

I think though in the broader respect of will this be able to be used with physician behavior, because I am sure that is necessarily part of it. I think what really fascinates me are some of the studies that have come out—and boy, I wish I understood them better—when these same type of studies as far as geographic variation and use and utilization of procedures etc cetera, were done in different settings like in the United Kingdom and in VA hospitals where they are on an entirely different reimbursement setup.

What was fascinating is that they found the same variations. Now, I wish I understood those. I think this is what we have to look at more, so that I guess that those studies tell me—will this absolutely change that? I am not sure yet. I think we have to look at that much, much more closely, Mr. Chairman.

Chairman STARK. There are some practice guidelines, I am informed now. I am not really familiar, but if there aren't correct me, but I'm informed that there are many of them developed. Are physicians using them now? And should they not, and if they are not using them, what do we do? We don't have to wait until we have, every one of 2,000 procedures to find, can't we start using some now, or is there some reluctance?

Dr. SEWARD. I can answer that to a certain degree, Mr. Chairman. I think one of them was, that we have all used here in this room, and it was probably developed over 50 years ago by the American Academy of Pediatrics, was guidelines on the use of immunization. It is one I still use in my practice. What is interesting to note is that they also studied, 50 years ago, a guideline on how to treat the common cold. I think that one is still dynamic and changing, Mr. Chairman. But yes, we are using guidelines now that to me—I know in my private practice in family medicine—I found truly helpful, truly helpful in that regard, and I think also reassures my patients that these are the guidelines that are put out for immunization. I think the cardiology ones, the ones put out by anesthesia now, the American College of Physicians have a number of guidelines that they have put forward which physicians are following.

Chairman STARK. Dr. Griner.

Are there enough guidelines out there now to get started, or is this something we have to wait 3 or 4 years to build up a library on before we act?

Dr. GRINER. Let me just reinforce the point that my colleague from the AMA just made, and that is that guidelines are not new. They have been in effect, one way or another, since, well, at least since Greco-Roman times. And a medical textbook is a guideline, a set of guidelines. What we are really, I think, trying to focus on is to develop guidelines in ways that are more precise, more individual-patient-specific, through the generation of better knowledge than we have had in the past.

And so, yes, the answer to your question is, yes, but we need the refinement and the added science.

Dr. DETMER. If I could just add briefly to that?

Chairman STARK. Please.

Dr. DETMER. I think that what the computer-based patient record gives us some of the potential ultimately to do is to address the comment of Dr. Leape who said, "What does the individual patient need when he comes to the individual physician for his care?" One of the things that the computer systems allow you to do is to get this more specific information, that Dr. Griner was just talking about, from the data base that's available. So guidelines can also, then, come up on the screen at that point to help actually give more precise information on just that type of patient with that type of problem.

I think that guidelines are a critical development.

Dr. MULLEY. Just an additional response to your question about guidelines.

Chairman STARK. Yes, please.

Dr. MULLEY. And also harkening back to your comment about professional autonomy. I think one of the reasons that guidelines may or may not be acceptable, depending on the different guideline, is that the physician knows that there is a certain amount of uncertainty that has to be glossed over in coming down in one direction or another. The physician also knows that different patients have different wants and needs and preferences for the same health outcome, and those things have to be glossed over in coming down on one side rather than the other.

So it isn't just a matter of preserving professional autonomy for the sake of autonomy; it is concern about a kind of micromanagement of the individual health care decisions that could lead to real inefficiency in that some people would get things that they don't want. There is a great unspoken concern here about supplier-induced demand. The other side of that is that other patients would not get things that they do want. To the extent that you could design a system, including guidelines, that would match the interventions to what people would choose—from the economist's point of view—that is clearly going to be more efficient in producing value, than basically setting a set of guidelines that would treat patients as if their attitudes toward uncertainty and their attitudes toward the health states are homogeneous when they are not.

Dr. SEWARD. Mr. Chairman, can I add a personal thing here?

Chairman STARK. Sure.

Dr. SEWARD. I know this concerns me, that I would love to have a more specific guideline on, in my family practice, and this has to do with the treatment of breast disease, which is a common thing that I see in my office. I can call my radiologist friend and he will give me one aspect and I think I am pretty good at solving problems because I can ask all of these experts. Then I go to my surgeon and he says, well, we should cut that thing out of there. I go to my gynecologist and he said, no, we will treat it with drugs and all of a sudden I still had my patient here—and others say, well, why don't I use this new technology of stereotaxic biopsy which causes less troubles. It is one of the new technologies. The point is, on that guideline, my patient—as it was stated before—would love to be able to know what is best at that point, because they——

Chairman STARK. The patient would like a pill rather than to get cut.

Dr. SEWARD. She wished it didn't happen and I can understand her being in absolute terror over this, and especially when I come back with five possibly different—you know—opinions on what is the best way to do this. This also then relates to cost. If we had a good guideline I know, as a practicing physician, I could say—you know—for instance on that disease, it would be used tomorrow, it would be used tomorrow.

Chairman STARK. I have mixed emotions. For some reason, I don't want to be talked into some things that I know maybe I ought to do because I know it is going to hurt, or be uncomfortable, or worse. And on the other hand, I don't want to be talked out of something because somebody tells me that it may have a 70-percent chance of making me feel better and my doc says, "naw, it has only got a 30-percent chance." I still probably want it, if I don't think it is going to hurt, and I can do it on the weekend.

So I don't know what this is going to do for me. Maybe ignorance is bliss, to some extent. Maybe you all ought to know as professionals, but I don't see any solutions. I mean, it makes Dr. Sullivan's exercise part of it, at least his litany looked a little better as a solution.

Mrs. Johnson.

Mrs. JOHNSON. Thank you, Mr. Chairman.

I am sorry I couldn't be here during your presentations. It is a subject that interests me a great deal. But I do have a couple of questions.

Chairman STARK. They said nice things about you while you were gone.

Mrs. JOHNSON. Dr. Detmer, in looking at the challenge that hospitals are going to face in implementing technology that will give them the ability to provide computer-based patient management, what are we going to be really asking, for instance, community hospitals to do? How difficult is it going to be for them to do? How costly is it going to be for them to do?

I have run those kinds of proposals by a couple of my, medium-sized hospitals, and actually I was surprised that their response wasn't more negative. They seemed to feel that they are going to get a lot of benefit from it, as well. Their primary anxiety was that we would push them too fast and before the technology was affordable.

Could you comment on a pace, on affordability, and on the usefulness for the ordinary hospital?

Dr. DETMER. Yes, I think this a very good question. I think the last estimate I saw was that hospitals around the Nation would be investing something like $9 billion in hospital information systems this year. That may be off a bit, but we already are spending—in other words—as a system, a fair amount of money on this.

But I think the committee is suggesting that we are talking about an infrastructure front-end investment, and, in fact, helping the industry do that—I think—is ultimately going to be in the system's aggregate benefit downstream.

How quickly systems will be coming along, will be a matter of how I would say how quickly we can get this partnership going—between the public and private sectors—to really start looking at that, target it at different sizes of institutions, target it at different

settings. The need of a rural practitioner in western Virginia is quite a bit different from somebody that is in a tertiary care hospital in Washington.

So there is a spectrum there. But we really do believe that the technologies are close enough—and maturing quickly enough—that we could, in fact, really have this largely addressed by the end of this decade.

Mrs. JOHNSON. Dr. Mulley, following along the same lines, Dr. Wilensky said something this morning that interested me and that I think is true. That was, if we make change in such a way that we lose the confidence and support of the provider community—physicians, hospitals, visiting nurse associations, you know, a whole group of folks out there—the risk of eroding quality is very great. I mean if you create an environment in which you have enemies rather than friends, the likelihood that you are going to erode the remarkable quality of the American medical system which does allow progressive change, is very great.

In your evaluation of the PRO's, you have seen a good deal of that tension, that is created between oversight and providers. In many hospitals, at certain periods, and in many communities, this has been an extraordinarily antagonistic relationship. Where it is not antagonistic, it has been extraordinarily productive, I think, for all parties. From your work in looking at PRO operations, and as we look to the future where clearly if we have guidelines there is going to be a different PRO relationship—are there things that you would suggest to us that we should focus on so that we can build positive relationships rather than negative relationships?

Others on the panel might want to comment on that, as well.

Dr. MULLEY. Yes, I think there are a number of suggestions that I could make based on the committee's findings and deliberations. I think it is very important to make the distinction between information—that is, data that can be collected—and new knowledge that is going to be helpful. I think it would be a terrible mistake to throw a lot of data at the joint problem of health care quality and cost containment.

The distinction between information, data, and knowledge is also important because knowledge is power and power threatens, and that's part of the tension we felt when we made our site visits and heard testimony.

The tension is very real. I think the way to reduce the tension is to link the kind of data base that we were proposing, and that you are proposing to the objectives of outcomes research as the committee did.

The point is that the current system collects a lot of data, that contributes no new knowledge, to deal with the professional uncertainty that underlies practice variation. It just doesn't do that. It creates data about adherence to standards, or guidelines, or something that the profession generally doesn't believe is useful.

If there are questions about the standards, and what you are doing is spending $330 million a year for the PRO's to collect data about that, and then each hospital is spending a goodly amount to be reactive to that kind of data collection, you have created an industry that is separate, parallel, creating no new knowledge to deal with the sentinel problem of quality and efficiency.

Mrs. JOHNSON. Is the tension the consequence of the generality of the data, versus the specificness of the case? Is there fear on the part of a provider that the nature of the individual situation is not going to be visible or attended to in the context of general data? Is that what you are saying? When you say, "better data," what you mean is more case-specific?

Dr. MULLEY. There are two things that the well-intended professional is interested in from the kind of data that could be collected or the kind of information and knowledge that could be generated. First, how likely are my patients to do better if I intervene with one approach as opposed to another? That kind of comparative outcome data looking at interventions—a surgical intervention versus a medical intervention, for instance—gets right at the heart of what the professional needs to know in order to do his job better, whether we are talking about an individual provider or whether we are talking about an institution.

If the system is designed to collect that kind of data, it will be viewed as the kind of navigation system for the profession that I was referring to.

The second kind of comparative information that could be produced by such a system, is comparison of rates of outcomes for the same intervention provided by different providers. Now, currently that is quite threatening to the profession.

Mrs. JOHNSON. Say that again, rates of outcome?

Dr. MULLEY. Rates of outcomes. What we're talking about on the one hand is if I do surgery for this patient, or I do a medical intervention for this patient, what is the likely outcome?

Mrs. JOHNSON. Oh, I see, the frequency of positive results from a certain intervention, a specific same intervention?

Dr. MULLEY. Right.

Mrs. JOHNSON. OK, thank you, I am sorry.

Dr. MULLEY. But in the first case I am talking about a very important distinction between gathering information that will give the professional more information about what is likely to happen to a patient if I do A or B, which the profession is hungry for, should be, has to be; as opposed to comparative rates among different providers all providing intervention A.

Chairman STARK. That is threatening.

Dr. MULLEY. That's threatening.

Chairman STARK. Like a hospital study. Hospitals don't like you to publish information about how many people die in their operating room as opposed to the next hospital. That is threatening.

Dr. MULLEY. Right. Let me give a specific example.

Mrs. JOHNSON. Comparative rates of success of a certain cardiac procedure?

Dr. MULLEY. Let me give a specific example. Let's talk about bypass surgery versus medical therapy. We could put in place systems, that would collect data, that would teach us how often surgery works more effectively than medical therapy. That same information system would—as a byproduct—give us, if it was used by a wide number of different institutions that were comparative, for instance, then it would give us information as a byproduct about what happened to people who got cardiac surgery at one institution, as opposed to another institution.

I think one argument the committee would make is that if that comparative rate information that would allow well-intended professionals—whether they be individual surgeons, or individual institutions—to know how they measure up against their colleagues, against their peers, if that is a byproduct of a system that is also producing information about whether they ought to be operating on that patient in the first place, or giving them a pill, it has a whole different feel to it for the profession.

It is constructive. It is dealing with the professional uncertainty that is at the root of practice variation, and at the same time, it is providing a stimulus for continuous quality improvement for those institutions that fit anywhere on the distribution of good or bad outcomes.

Mrs. JOHNSON. Could you contrast this to data that is developed, that creates tension, that is not useful?

Dr. MULLEY. Yes. What I am saying is that those two forms of data would be very useful for the well-intended professional.

Mrs. JOHNSON. I understand that. What kinds of data have we been developing, that have created so much tension, that is not productive?

Dr. MULLEY. Well, if we set a standard for when we ought to do intervention A—when the profession feels that there really is not very good evidence to determine that it is black and white, that you should do it in this circumstance or you should not, and that the profession really feels that the motivation is mixed—yes, you are looking out for the quality of care, but you are also concerned about the costs of the care, and then you measure adherence to that standard, that has a whole different feel to it.

There are only comparative rates as opposed to information that tells the doctor whether A works better than B, if there are only comparative rates for different providers, with the one intervention, that is problem No. 1.

Mrs. JOHNSON. Thank you.

Dr. MULLEY. And problem number two is that it doesn't do anything to increase the knowledge base.

Mrs. JOHNSON. Thank you, that helps.

Any other comments?

Dr. GRINER. If I may, Mrs. Johnson, I am Dr. Griner and I direct a university teaching hospital. I would like to respond to the issue of external oversight. There is a very important issue that goes beyond the tensions that have just been described, and that relates to the enormous amount of duplication of wasteful duplication of external oversight functions that occur, none of which are coordinated. So we have, for example, very legitimate and important review functions served by the joint commission, by the State departments of health, by PRO's for Medicare, by similar review programs for Medicaid. And in our case, we have 15 different utilization review programs of various private payors.

So we are responding to 19 separate external oversight functions, none of which are coordinated, all of which have different systems—and the complexity as information management technology expands—I think you can get the picture of the amount of the waste that is occurring.

We need somehow to develop a more coordinated and integrated approach to external oversight, perhaps stimulated by some of the common infrastructure that Dr. Detmer was referring to.

Dr. DETMER. Yes, I think this was one of the points that we had made is that not just physicians—we have talked a lot about physicians—but an array of health professionals of different types, all have their own unique needs. So these layers of needs to respond to different outside groups, wanting different kinds of things, is one thing that complicates it.

What we see coming is a computer-based patient record—and you will notice the term is "patient record", not "medical record", and the reason why is that there are a lot of users with different needs. And the focus of this should be the patient and that is why the report uses that title.

But basically we see that there are all sorts of opportunities to actually reduce some discontinuities and these layers including even streamlining some administrative things, like direct payments from computer systems.

Mrs. JOHNSON. I think that two of the things that we ought to be able to address in the near term, while we build consensus on what else to do, is dealing with this issue of duplicative actions. The oversight area is not something that I am able to know what to do about, but it is something that I have heard about for so long that I hope you all will take the initiative to try and get your organizations to recommend some simplification. How do we move from where we are now, which is getting worse, toward a single oversight system? The revolution that it is going to take to get to a single-payor system in terms of national opinion and consensus building is some years, maybe lots of years down the road.

But there ought to be a way to do something about the payor problems, I mean I feel a sense of urgency about this duplication of oversight. If we are going to move toward the computerization that will give us much better knowledge and much better ability to manage and give parties better information about courses of action—all things that we want to do—can't we combine that with some reduction in the duplication of review processes?

Anything written you could give us on that, I think all of us on the committee would be interested in that.

Thank you.

Thank you, Mr. Chairman, I appreciate that.

[The following was subsequently received:]

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INSTITUTE OF MEDICINE

May 3, 1991

Robert J. Leonard
Chief Counsel
Committee on Ways and Means
U.S. House of Representatives
1102 Longworth House Office Building
Washington, D.C. 20515

Dear Mr. Leonard:

On April 30, members of the Institute of Medicine (IOM) testified at your hearing on medical care quality and outcomes research. Their testimony focused on IOM reports on the patient medical record and on quality assessment and assurance in the Medicare program. Some of the testimony from other organizations dealt with practice guidelines, and we were then asked if we could also submit written testimony on this topic.

We hope that you will find the enclosed statement helpful. It is based, for, the most part, on the summary of the Fall 1990 IOM report Clinical Practice Guidelines: Directions for a New Agency. A second IOM report on guidelines, as mentioned in the statement, will be issued this Fall.

If you have any questions, please feel to contact the study director, Dr. Marilyn Field, at 202-334-2360. Thank you for this opportunity to discuss the results of our work in this area.

Sincerely yours,

Enriqueta C. Bond

Enriqueta C. Bond, Ph.D.
Executive Officer

cc: Samuel Thier
Marilyn Field
Kathy Lohr
Karl Yordy
Brian Biles
Chip Kahn

STATEMENT FOR THE RECORD ON
CLINICAL PRACTICE GUIDELINES
FROM THE INSTITUTE OF MEDICINE, NATIONAL ACADEMY OF SCIENCES

FOR THE HEARING ON
MEDICARE QUALITY OF CARE, AND OUTCOMES AND EFFECTIVENESS RESEARCH

THE SUBCOMMITTEE ON HEALTH
THE COMMITTEE ON WAYS AND MEANS, U.S. HOUSE OF REPRESENTATIVES

APRIL 30, 1991

In October 1990, the Institute of Medicine (IOM) of the National Academy of Sciences published an initial report on clinical practice guidelines, and it is now engaged in a second study that should be published at the end of this year. This summary provides an overview of the IOM work to date, highlighting some issues evidently of concern to the Health Subcommittee of the Ways and Means Committee of the Congress of the United States. The first part of this testimony draws heavily on the summary of Clinical Practice Guidelines: Directions for a New Program (M.J. Field and K.N. Lohr, editors; National Academy Press, 1990). The second part describes current efforts.

FIRST IOM STUDY: ADVICE TO A PUBLIC HEALTH SERVICE AGENCY

In 1989, the Congress created the Agency for Health Care Policy and Research (AHCPR) within the U.S. Public Health Service and gave it broad responsibilities for supporting research, data development, and other activities to "enhance the quality, appropriateness, and effectiveness of health care services...." Among these other activities were support for the development of clinical practice guidelines through a Forum on Quality and Effectiveness.

AHCPR immediately requested advice from the IOM on how it might approach its new responsibilities for practice guidelines. The IOM appointed an expert study committee that included practicing physicians, individuals experienced in the development of guidelines, current and potential users of guidelines, and representatives of relevant other disciplines such as nursing, law, and economics. That committee, under a very short deadline, provided advice on definition of terms, specification of key attributes of good guidelines, and certain aspects of planning for implementation and evaluation. The ensuing report was not a how-to-do-it manual, a methodology text, a priority-setting exercise, or a primer on guidelines for those seeking an introduction to the subject. It did, however, aim to encourage more standardization and consistency in guidelines development, whether such development is supported directly by the agency or is undertaken independently by medical societies and other organizations. It also sought to encourage realistic expectations by building a broader understanding of the difficult but important steps needed to move toward the goals for practice guidelines stated by the Congress.

CONTEXT

The IOM committee began its work with an understanding that the legislation establishing AHCPR is one consequence of accumulated public and private frustrations about the perceived health and economic consequences of inappropriate medical care. These frustrations and perceptions stem from many sources including ceaselessly escalating health care costs, wide variations in medical practice patterns, evidence that some health services are of little or no value, and claims that various kinds of financial, educational, and organizational incentives can reduce inappropriate utilization. The combination of high expenditures and doubts about the value of that spending explains policymakers' interest in improving the scope and application of knowledge about what works and what does not work in medical care--and at what price.

More generally, the creation of a practice guidelines function within AHCPR can be seen as part of a significant cultural shift, a move away from unexamined reliance on professional judgment toward more structured support and accountability for such judgment.

Reflecting one element of this shift, guidelines are intended to assist practitioners and patients in making health care decisions; reflecting the second aspect, they are to serve as a foundation for instruments to evaluate practitioner and health system performance.

As the interest in practice guidelines has grown, so has the scrutiny of existing guidelines and of processes for developing and using them. This scrutiny leads to one clear conclusion: the systematic development, implementation, and evaluation of practice guidelines based on rigorous clinical research and soundly generated professional consensus, although progressing, has serious limitations in method, scope, and substance. Concerns about these and other problems with practice guidelines contributed to the legislation creating AHCPR and the Forum.

OVERVIEW OF PRACTICE GUIDELINES INITIATIVES

Public and private activities related to practice guidelines can be conceptualized, ideally, as having three basic stages: development, intervention, and evaluation. The second and third stages should--again ideally--involve feedback loops to the first stage to prompt the revision of guidelines when omissions, technical obsolescence, or other problems with a set of guidelines are identified. Guidelines are thus dynamic, not static. They reflect the interplay of scientific and technological progress, real-world organizational pressures, and changes in social values.

To date, most government and other initiatives emphasize the first of the three stages, the development of guidelines. The intervention stage involves much more diffuse and less studied efforts to disseminate guidelines to targeted users and to encourage them to apply the guidelines in making health care decisions. Only recently has much attention been paid to evaluating whether and why guidelines have any impact.

Guidelines for clinical practice, broadly defined, are not new. The processes of organized clinical education require various sorts of guidelines, as do the processes of professional licensure, board certification, quality assurance, utilization review, and other aspects of health services administration. However, the interest of the medical community and others in practice guidelines has grown exponentially in recent years. Moreover, there is much more emphasis today on formal procedures and methods for arriving at a more widely scrutinized and endorsed consensus.

The guidelines development efforts of private organizations are proceeding on many fronts. Some coordinating strategies are emerging, but important problems remain--unexplained conflicts among guidelines, neglected topics, lack of follow-up, and incomplete public disclosure of the evidence, participants, and methods used to develop sets of guidelines. No independent entity exists to certify that guidelines are sound in method and content, and no "national bureau of standards" is available to set standards for methods of guidelines development or their content.

FINDINGS AND CONCLUSIONS: STATE OF THE ART

The IOM committee arrived at several general observations about the state of the art of practice guidelines development. Most generally, the systematic development, implementation, and evaluation of practice guidelines based on rigorous clinical research and soundly generated professional consensus, although progressing, has deficiencies in method, scope, and substance. Conflicts in terminology and technique characterize the field; they are notable for the confusion they create and for what they reflect about differences in values, experiences, and interests among different parties.

Public and private development activities are multiplying, but the means for coordinating these efforts to resolve inconsistencies, fill in gaps, track applications and results, and assess the soundness of particular guidelines are limited. Disproportionately more attention is paid to developing guidelines than to implementing or evaluating them. Moreover, efforts to develop guidelines are necessarily constrained by inadequacies in the quality and quantity of scientific evidence on the effectiveness of many services.

The committee noted that the AHCPR not only began with this limited foundation but faced challenging legislative requirements that it develop its first three guidelines within little

more than a year following the legislation creating the agency. It was also to evaluate and report to Congress on the impact of these guidelines of the cost, quality, effectiveness and appropriateness of medical care within the following two years. In fact, the agency has not met the first deadline and cannot practically meet the second in more than a perfunctory fashion.

Within the government, meeting the challenge of developing good practice guidelines cannot be solely the responsibility of the Forum. For instance, the AHCPR's Medical Treatment Effectiveness Program (MEDTEP) will generate information of immediate importance for practice guidelines. Moreover, lacunae in data identified during the guidelines development process should highlight areas that AHCPR can target for research funding. Outside AHCPR, the work of other agencies in the Public Health Service (PHS), most notably the National Institutes of Health, will be essential to the long-term utility of guidelines, especially insofar as those trials include broad measures of outcomes important to patients. Outside the PHS, the agency has established some links with the Health Care Financing Administration, in part because of provisions of OBRA 89 but more importantly because HCFA's data on the Medicare population (and, to a lesser extent, on the Medicaid population) should be valuable for developing, implementing, and evaluating guidelines. In addition, the Peer Review Organizations may be valuable sites for disseminating guidelines, using them as quality review criteria, and evaluating their practical utility.

Although this IOM report focused on AHCPR, it also noted that government's role in arranging for the development of practice guidelines may in the end be fairly modest. Indeed, the contemporaneous efforts of many different organizations in the private sector may significantly outpace what this one agency can do. The predominance of the private sector should be even greater for guidelines implementation, where most initiative must rest with private organizations and individuals. Even when the government plays the principal role in funding and disseminating guidelines on certain topics or clinical conditions, these guidelines will be tailored or adjusted by patients, practitioners, providers, health plans, and others to reflect different patient populations, delivery settings, practitioner skills and attitudes, levels of resources, perceptions of risk, and other factors. The committee expects that the processes of guidelines development, implementation, and evaluation will always need to be pursued by both the public and private sectors.

RECOMMENDATIONS: DEFINITIONS

The legislation creating AHCPR used four key terms in its assignment of responsibilities to the agency: (1) practice guidelines, (2) medical review criteria, (3) standards of quality, and (4) performance measures. Neither the final legislation nor preceding House or Senate bills offered definitions of these particular terms, and the literature on practice guidelines and related topics is characterized by significant diversity in common and professional usage. To meet the agency's need for clear and broadly acceptable definitions of these terms, the study committee sought definitions that were--insofar as possible--parsimonious, clear, not tautological, consistent with customary professional and legislative usage, and socially and practically acceptable to important interests.

The committee recommended that the agency work with the following definitions.

PRACTICE GUIDELINES are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.

MEDICAL REVIEW CRITERIA are systematically developed statements that can be used to assess the appropriateness of specific health care decisions, services, and outcomes.

STANDARDS OF QUALITY are authoritative statements of (1) minimum levels of acceptable performance or results, (2) excellent levels of performance or results, or (3) the range of acceptable performance or results.

PERFORMANCE MEASURES (Provisional) are methods or instruments to estimate or monitor the extent to which the actions of a health care practitioner or provider conform to medical review criteria and standards.

These definitions cannot resolve all arguments over what these and related terms mean, but the IOM committee expected--and we have seen some evidence for this since the first report was published--that the four statements will bring greater clarity and uniformity to the field. The agency has accepted these definitions, and they are increasingly used by other organizations, although many continue to prefer other terminology.

One underlying premise highlighted by these definitions is that these four terms are not synonymous. Assisting physicians, nurses, other practitioners, and patients in making decisions (through practice guidelines) is not the same as evaluating practice (using medical review criteria, standards of quality, and performance measures). Therefore, although the definitions may evolve, it is important to underscore that the phrases and concepts are not equivalent and should not be used interchangeably. Those who use other terms should make clear whether they have these--or other meanings--in mind.

Not part of the committee's definition of practice guidelines, but central to its view of the field, is the precept that every set of guidelines should be accompanied by a statement of the strength of the scientific evidence and the expert judgment behind them and by projections of the relevant health and cost outcomes. The committee has not tried to distinguish types or levels of practice guidelines (for example, Levels 1 or 2), although this type of discrimination may be useful.

RECOMMENDATIONS: ATTRIBUTES OF GOOD GUIDELINES

Developing practice guidelines is a challenging task that requires diverse skills ranging from the analysis of scientific evidence to the management of group decisionmaking to the presentation of complex information in understandable forms. Sponsors of guidelines must be able to state to expert panels and other involved parties what their expectations are for the process and its products. (The legislation creating AHCPR calls this establishing "standards and criteria" for the process. To avoid confusion, the committee substituted the term "attributes" for the statutory language.)

The study report distinguished between the priorities for selecting particular targets for guidelines and the desirable attributes of guidelines. Priority setting is a crucial but separate task for which OBRA 89 provides guidance.

Drawing on its members' experience and expertise and the work of past IOM committees and other relevant organizations, the committee recommended that the agency use the following eight attributes, properties, or characteristics to instruct expert panels or contractors and to assess their products. The attributes focus on practice guidelines and not on medical review criteria and other tools for evaluating practice. The first attribute--validity--is the most important and complex one.

VALIDITY: Practice guidelines are valid if, when followed, they lead to the health and cost outcomes projected for them. A prospective assessment of validity will consider the projected health outcomes and costs of alternative courses of action, the relationship between the evidence and recommendations, the substance and quality of the scientific and clinical evidence cited, and the means used to evaluate the evidence.

RELIABILITY/REPRODUCIBILITY: Practice guidelines are reproducible and reliable (1) if--given the same evidence and methods for guidelines development--another set of experts would produce essentially the same statements and (2) if--given the same circumstances--the guidelines are interpreted and applied consistently by practitioners or other appropriate parties. A prospective assessment of reliability may consider the results of independent external reviews and pretests of the guidelines.

CLINICAL APPLICABILITY: Practice guidelines should be as inclusive of appropriately defined patient populations as scientific and clinical evidence and expert judgment permit, and they should explicitly state the populations to which statements apply.

CLINICAL FLEXIBILITY: Practice guidelines must identify the specifically known or generally expected exceptions to their recommendations.

CLARITY: Practice guidelines must use unambiguous language, define terms precisely, and use logical, easy-to-follow modes of presentation.

MULTIDISCIPLINARY PROCESS: Practice guidelines must be developed by a process that includes participation by representatives of key affected groups. Participation may include serving on panels to develop guidelines, providing evidence and viewpoints to the panels, and reviewing draft guidelines.

SCHEDULED REVIEW: Practice guidelines must include statements about when they should be reviewed to determine whether revisions are warranted given new clinical evidence or changing professional consensus.

DOCUMENTATION: The procedures followed in developing guidelines, the participants involved, the evidence used, the assumptions and rationales accepted, and the analytic methods employed must be meticulously documented and described.

The stringency of these attributes, especially taken together, is well recognized. Realistically, neither existing guidelines nor those likely to be developed by the agency in the foreseeable future will "score well" on all eight properties simultaneously. Indeed, near-perfect scores may always lie in the realm of aspiration rather than attainment. Moreover, the process of developing, assessing, using, evaluating, and revising guidelines will be evolutionary. There is today no proven "right way" to conduct this endeavor, even if there clearly are some "better ways." In addition, a balance needs to be maintained between an ideal process and one that is feasible. Guidelines that satisfactorily reflect the eight attributes proposed here may not be products of an ideal process, but in the committee's view they will be defensible.

The link between a set of guidelines and the scientific evidence must be explicit, and scientific and clinical evidence should take precedence over expert judgment. Every set of guidelines should be accompanied by a clear statement of the strength of the relevant scientific evidence and expert judgment. When the empirical evidence has important limitations and experts reach conclusions that are not consistent with the evidence, then the rationale for departing from the evidence, such as it is, should be carefully explained. When expert judgment proceeds in the absence of direct empirical evidence about a particular clinical practice, the general scientific reasoning and normative principles supporting the judgments should be described.

The first report on guidelines did not take a position on whether cost considerations should be explicitly factored into practice recommendations, although some committee members had strong views that they should be. However, documentation of projected health outcomes and costs is important to help developers and users of guidelines better understand the implications of following or not following the guidelines.

One of the committee's strongest recommendations was that the process of developing guidelines include participation by representatives of key affected groups and disciplines. Such participation increases the likelihood (1) that all relevant scientific evidence will be located and critically evaluated; (2) that practical problems with using the guidelines will be identified and addressed; and (3) that affected groups will see the guidelines as credible and will cooperate in implementing them. Participation by physicians, nurses, patients, and others can be achieved in several ways including membership on the development panel, testimony at public hearings, participation in focus groups, consultation during site visits, and provision of comments on draft guidelines.

RECOMMENDATIONS: IMPLEMENTATION AND EVALUATION

Although AHCPR is responsible for implementing the government program for guidelines established in OBRA 89, the main work of implementing the guidelines themselves will be in the hands of physicians, nurses, health care administrators, and others. The agency, however, has important responsibilities for disseminating guidelines and evaluating their impact. The committee's discussions were limited by its charge and centered primarily on how the processes of implementation and evaluation can reinforce and extend the eight attributes of guidelines defined earlier.

A starting point is that those developing guidelines should keep implementation and evaluation in mind as they develop guidelines. The tension between extraordinarily detailed, complex, or sophisticated guidelines and those that can be translated into usable medical review criteria, or into documents that can be understood by the average patient, must be recognized and dealt with during the development process, not after the fact.

Keeping implementation and evaluation in mind means, among other things, understanding the following

- o The credibility of the development process, the participants, and the scientific grounding of guidelines must be clear to intended users.
- o One advantage of a truly multidisciplinary approach to guidelines development lies in facilitating acceptance and use of guidelines by members of the groups represented and by other, secondary target groups.
- o Guidelines should be specific, comprehensive, and flexible enough to be useful in the varied settings and circumstances of everyday medical practice and in the evolving programs to assess the appropriateness of care provided in these settings.
- o Guideline language, logic, and symbols should be easy to follow and unambiguous, so that movement from guidelines statements to educational tools, review criteria, or other instruments is unimpeded.
- o The guidelines should specify what information about the clinical problem, the patient's circumstances and preferences, and the delivery setting should be recorded to permit later evaluation of the appropriateness of care (judged against criteria generated from the guidelines).

The implementation of guidelines is a diffuse, difficult-to-track process that will depend on many factors besides the quality and credibility of the guidelines. Among those factors are (1) the funding for dissemination and other implementation activities; (2) the incentives and supports for the guidelines to be used by physicians, nurses, health plans, and others; (3) the accessibility, scope, accuracy, and timeliness of a variety of intra- and interorganizational information systems; and (4) the ability of multiple parties to plan and execute the various steps needed to implement guidelines.

Users of guidelines will vary in their objectives, commitment, and circumstances, and strategies for meeting particular objectives will differ in their cost-effectiveness and manageability. Thus, different objectives and resources may call for different choices among the formats for guidelines (that is, their physical layout and logic), different roles for the available dissemination media, and different kinds of administrative supports for users of guidelines. Organizations with more resources (for example, libraries, video centers, personal computers, telephone hotlines, and network information systems) will be able to assist the use of guidelines in ways that are out of reach for less resource-rich organizations.

Medical review criteria and other evaluation instruments, if properly developed and sensitively applied, can create incentives for adherence to practice guidelines. If improperly developed and applied, they can undermine support for practice guidelines. Building on earlier IOM reports on utilization management and quality assurance, the committee discussed a few broad principles for the constructive use of medical review criteria and other evaluation tools derived from practice guidelines.

First, review criteria should be public with respect to their content and their development process. Second, when criteria are used to assess quality of care, deny payment for specific services, or take similar steps, an appeals process must be provided that is free from unreasonable complexity, delay, or other barriers. Third, review organizations should provide constructive information and feedback to physicians and other clinicians with the aim of improving practice rather than punishing missteps.

Fourth, review organizations should make their review activities as manageable and nonintrusive as possible. Such organizations contribute to the perceived and real "hassle factor" in medical care, which grows out of burgeoning demands by payers and others for more information on, and justification for, health services delivered or proposed. The Forum needs to be sensitive to this issue. It also should work with HCFA and other organizations to

minimize negative effects from poor translation of otherwise good guidelines into review criteria, unduly stringent application of these criteria, or both.

DIVERSITY IN CLINICAL PRACTICES AND GUIDELINES

In its discussions, the IOM committee repeatedly returned to questions of diversity in clinical practice and inconsistency among guidelines. Diversity in clinical practice can be acceptable or unacceptable. It may be reasonable when the scientific evidence to support different courses of care is uncertain. In addition, some degree of diversity may be warranted by differences in individual patient characteristics and preferences and variations in delivery system capacities related to locale, resources, and patient populations. However, even though practice variation based on scientific uncertainty or differences in values may be acceptable, both science and values are open to change. Thus, what is perceived as acceptable diversity in clinical practice may change over time.

Diversity in practice is unacceptable when it stems from poor practitioner skills, poor management of delivery systems, ignorance, or deliberate disregard of well-documented preferable practices. It should not be tolerated when it is a self-serving disguise for bad practices that harm people or waste scarce resources.

Guidelines can clarify what is acceptable and unacceptable variation in clinical practice, but that clarification itself has limits that may lead different groups to different and even inconsistent guidelines. Weak evidence is still weak evidence, although the processes described in the IOM report should allow the best use of whatever evidence is available. Nonetheless, these processes still leave room for differences of expert opinion about such issues as whether a flaw in research design "matters" or whether differences in results between two treatment alternatives are "clinically important" or only "statistically significant."

Inconsistency among guidelines can also arise from variations in values and tolerance for risk. People may simply differ in how they perceive different health outcomes and how they judge when benefits outweigh harms enough to make a service worth providing. One way to approach this kind of variation is to try to establish practitioner and patient attitudes toward different benefits and harms and, then, identify what is known about the probabilities of those different outcomes. In some cases, the developers of guidelines take the further step of applying their own values, but others considering the guidelines later could look at the same information and perhaps come to different conclusions. Also, for some services and clinical conditions, the developers of guidelines may choose not to recommend a single course of action but to lay out alternative courses of treatment that may be appropriate depending on, for example, the preferences of a patient or the characteristics of a delivery setting or community.

In sum, merely identifying inconsistencies in guidelines says nothing about the legitimacy of those inconsistencies. Some inconsistencies may arise from biased or inept development processes. Some may result from reasonable differences in the interpretation of scientific evidence or in the application of patient, practitioner, or social values. Other inconsistencies may essentially disappear when the rationales for specific recommendations are closely examined. The challenge is to determine which explanation applies. Meticulous documentation of the evidence and rationales for guidelines will make this determination easier.

CONCLUSION

Today the field of guidelines development is a confusing mix of high expectations, competing organizations, conflicting philosophies, and ill-defined or incompatible objectives. It suffers from imperfect and incomplete scientific knowledge as well as imperfect and uneven means of applying that knowledge. Despite the good intentions of many involved parties, the enterprise lacks clearly articulated goals, coherent structures, and credible mechanisms for evaluating, improving, and coordinating guidelines development to meet social needs for good-quality, affordable health care.

This situation will not change overnight, even though many promising activities, including those sponsored by AHCPR, are under way. Thus, expectations of quick results should be restrained. Otherwise, dashed hopes may lead to calls for premature abandonment of a useful

strategy for improving the appropriate use of health services and to the adoption of more draconian measures to control costs.

The committee is also concerned about other expectations or assumptions that may be unrealistic. One such assumption is that guidelines development is a relatively simple or straightforward undertaking. It is not. For many clinical conditions and services, the science base is limited. Methods for analyzing evidence and developing expert opinions vary, but none of the rigorous methods can be properly applied by novices. Even in cases where considerable research has been done and sound methods applied to analyze it, honest clinicians and analysts may still come to different conclusions from the same evidence. Agreement on facts may not be matched by agreement on what health benefits are desirable at which economic cost with what tolerable accompanying health risks.

Such conflicts about the interpretation of evidence and application of value judgments cannot be ignored. Indeed, the whole process of guidelines development has to be undertaken with great care at every stage: selecting participants, clarifying biases, adopting procedures and methods, identifying and analyzing evidence, considering alternatives, providing for independent reviews, preparing clear recommendations, and disclosing all important information about the process.

A second assumption of concern to the committee is that there is one right way to develop guidelines. There is not. Variations in the topics, the clinical disciplines involved, the purposes, and the audiences for guidelines will justify some differences in the specific methods for developing guidelines. However, to grant some methodological diversity is not to accept all approaches as equally good. Much remains to be tried and learned about the strengths and weaknesses of different methods.

A further questionable expectation, which is sometimes explicit but often unstated, is that practice guidelines will help control health care costs. They may not. The reasons for caution on this point are several. For instance, variation in practice does not, by itself, demonstrate that high-use patterns are necessarily the inappropriate ones. Moreover, even if high use can be identified as inappropriate, such identification does not automatically change behavior. An array of incentives for behavior change may be tried, but not all will succeed. And even if behavior changes, expenditures may not.

Some guidelines undoubtedly will save money by reducing the use of inappropriate services; some will increase costs by encouraging more use of underutilized services; and some will shift costs from one service or place or payer to another. The net impact on costs cannot be predicted with confidence, even if the priorities for guidelines development focus on clinical conditions for which overuse of expensive services is suspected. Nevertheless, if guidelines do succeed in improving the appropriateness and hence the <u>value</u> of this country's expenditures of medical care, then the endeavor will be a success.

This committee believes that the AHCPR's practice guidelines effort has real potential to advance the state of the art in this field, strengthen the knowledge base for health care practice, and, hence, improve the appropriateness and effectiveness of health care. The conditions for such success are demanding but not out of reach. In particular, expectations for the agency--and for practice guidelines per se--must be realistic regarding timetables and results. All parties concerned must act in good faith and keep the credibility and accountability of their actions in mind. Strict regard for the scientific rigor of the process is critical as is avoidance of premature closure on a single method of guidelines development. Attention to implementation and evaluation needs to be factored into the development process at an early stage.

The Forum can underscore its intent to examine critically and improve its program and products in at least three ways. First, it should ask its expert panels for feedback on the strengths and weaknesses of the procedures followed. Second, it should pretest (or arrange for the pretesting of) all guidelines developed under its aegis. This can be done on a pilot basis in a real delivery setting, on a set of prototypical cases, or both. Third, it should try to evaluate the effectiveness of intermediate actions (for example, formatting, dissemination, incentives) that are necessary if guidelines are to have their intended effects on health practices, outcomes, and costs. Each of these steps can be part of a learning process for the Forum and others.

CURRENT STEPS FOR THE IOM: FORGING A FRAMEWORK FOR THE FUTURE

In May 1990, a new IOM committee began an 18-month study of the development, implementation, evaluation, and revision of clinical practice guidelines. Many of the issues raised above are being examined in greater depth during this second project, which is supported by the John A. Hartford Foundation, Inc. and the U.S. Public Health Service. In preparing its report and recommendations, the new committee will

- Describe existing initiatives to develop, use, evaluate, and improve guidelines for clinical practice and identify related societal objectives and concerns of specific groups.
- Assess the strengths and limitations of current efforts in light of the identified objectives and concerns.
- Based on these assessments, recommend a conceptual and practical framework for the future development, use, and evaluation of guidelines including such new public and private institutional arrangements as may be reasonable.
- Describe the timetable and the organizational, educational, financial, legislative, and other steps necessary to implement and support the recommendations.

The current IOM committee is drafting an instrument for AHCPR and others to employ in assessing guidelines before recommending or using them. This instrument aims to be a tool with which others can judge, first, the quality of the process by which a given guideline was developed and, second, the soundness of the guideline itself, by operationalizing the attributes defined earlier. Thus, it focuses on how the guidelines were developed, their scientific basis, their relevance to clinical practice, their clarity, and other characteristics. It is not a substitute for later evaluations by government and others of the impact of a set of guidelines.

A particular focus of this study is the implementation of practice guidelines. Although the processes of implementation are diffuse, complex, and difficult to track, the second IOM report will attempt to suggest what conditions will support the effective application of practice guidelines. The committee is examining how guidelines are (or are not) integrated in programs for quality assurance and improvement, health benefits design and administration, and medical risk management. Other issues are also being given considerable scrutiny. Among them are the bioethical aspects of guidelines and the status of guidelines in malpractice litigation.

The Institute would be pleased to provide additional information on these and other studies of interest to the subcommittee.

Chairman STARK. I want to thank the panel very much for their participation today and the committee is adjourned.

[Whereupon, at 1:09 p.m., the hearing was adjourned.]

[Submissions for the record follow:]

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STATEMENT OF THE AMERICAN COLLEGE OF RHEUMATOLOGY TO THE SUBCOMMITTEE ON HEALTH, COMMITTEE ON WAYS AND MEANS FOR THE APRIL 30, 1991 HEARING ON MEDICARE QUALITY OF CARE, AND OUTCOMES AND EFFECTIVENESS RESEARCH

The American College of Rheumatology (ACR) enthusiastically supports the Subcommittee's efforts in considering the promotion of outcomes research in medicine. ACR is the world's largest organization of rheumatologists, both physicians and scientists, dedicated to the prevention, treatment, and eventual cure of arthritis and the more than 100 types of related rheumatic diseases. As one of the first sub-specialty societies with an active interest in this area, the College formed last year the Committee on Health Care Research with the express intent of promulgating the development of practice guidelines based on explicitly analyzed outcomes. The College urges the Subcommittee to consider the following positions which we hold:

1) A major effort should be supported to develop outcome endpoint parameters other than death to measure the utility of medical practices. The leading killers in our country afflict primarily those who begin consuming health care dollars at an age when they have already retired from being producers of those dollars. However, arthritis and other musculoskeletal diseases afflict many who are in their earning years, converting active producers of health care dollars into consumers. In the 1980s, musculoskeletal diseases resulted in far more disability payments than did some of the leading killers, e.g., those resulting from cardiovascular diseases. Musculoskeletal diseases are second only to acute respiratory diseases in overall economic impact to this country when compensation paid, medical care costs, and disability payments are included. The College believes that outcome parameters that can quantify suffering, disability and degrees of functional impairment are considerably more important than death, for both humane and for economic reasons.

2) The College would encourage the Subcommittee to insist that any cost/benefit/outcome analysis include an analysis of the indirect costs of illness such as lost wages and productivity, disability benefits, etc. The leading killers do not have as much overall economic impact as arthritis and other musculoskeletal diseases.

3) The College strongly recommends that practice guidelines developed through outcomes research be explicitly derived rather than implicitly derived as has been customarily the case in the past. Explicit guidelines require a cost-benefit analysis based on real economic and medical data, whereas implicit guidelines generally represent only the aggregate opinion of a panel of experts, often with no basis in or attempt at developing pertinent economic facts on the issue.

In summary, the American College of Rheumatology would encourage the Subcommittee to promulgate the development of outcomes parameters for conditions having a greater economic impact than death. As a legitimate concern of the nation's health care effort, the College urges the Subcommittee to insist on explicit cost/benefit analyses in the development of practice guidelines, and that those analyses attend to the entirety of economic factors resulting from disease and not simply the health care costs involved.

The College stands ready to support the efforts of the Subcommittee in any way we can.

STATEMENT OF THE

AMERICAN SOCIETY OF INTERNAL MEDICINE

TO THE WAYS AND MEANS COMMITTEE

SUBCOMMITTEE ON HEALTH

HEARING OF APRIL 30, 1991

The American Society of Internal Medicine appreciates this opportunity to share with the subcommittee our views on Medicare quality of care, effectiveness research and practice guidelines. ASIM represents over 25,000 practicing internists across the United States and Puerto Rico. As one of the major supporters of the creation of the Agency for Health Care Policy and Research (AHCPR), we continue to believe that outcomes research and development of practice guidelines offer the best hope for appropriately addressing increases in volume of services without compromising the quality and availability of care. The ultimate goal is to educate physicians about those services that are ineffective or of marginal benefit to the patient so that they can be eliminated. At the same time, outcomes research and development of practice guidelines can provide physicians with the tools to assess various methods of treatment and assure that demonstrably effective services can be provided to patients. Finally, these steps should also pave the way for greater consistency in the medical review system so that physicians will have a greater assurance that appropriately provided services will be accepted by reviewers and paid for by insurers.

Congress created the Agency for Health Care Policy and Research in 1989 to enhance the quality, appropriateness and effectivess of health care services and access to such services through support of broad-based scientific research projects and promotion of improvements in clincial practice and the financing and delivery of health care services. Under the auspices of AHCPR, advisory panels are now completing work on guidelines for treatment of seven conditions that affect a large proportion of the Medicare population and account for a significant percentage of Medicare expenditures. Although the January 1, 1991 deadline for issuance of three guidelines was not met, ASIM believes that AHCPR and its leadership have done an admirable job of organizing and undertaking a very complex effort, involving the appointment and coordination of dozens of guidelines panels, the review of thousands of medical journals and documents, and the solicitation of public comments from around the country. ASIM applauds the appointment of Dr. Jarrett Clinton as permanent director for the agency.

ASIM would also like to point out that some useful and instructive information has already come out of several of the guideline panels' work. For example, the panel looking at guidelines for the treatment of benign prostatic hypertrophy, a disease of the prostate, discovered that a radiologic procedure often done as part of an exam for patients with BPH symptoms was in fact not very useful. Given that some 450,000 of these procedures are performed each year on BPH patients at a cost between $500 and $1000 each, this could represent a major savings to the Medicare program. Conversely, the panel investigating effective ways to treat and manage chronic pain found that post-surgical pain is undertreated, to the detriment of patients who would heal faster and better if given more attention to their condition. If federal policymakers do indeed support ensuring high quality health care for beneficiaries of government programs, they must accept the fact that some results of outcomes and effectiveness research may point to increased expenditures of funds as well.

As an early supporter of practice guidelines, ASIM recognizes its own responsibility to further their development for services and procedures provided by internists, to work with internal medicine subspecialty societies in support of this objective, and to educate internist-leaders on the role of the new agency. We also believe it is important to ensure that practicing internists are represented in all relevant guideline development activities so that the finished products are applicable to the everyday practice of medicine. In pursuit of these objectives, ASIM has worked to ensure that practicing internists are placed on the AHCPR guideline panels and on the AHCPR Advisory Council and has joined the AMA/Specialty Societies Practice Parameters Partnership to coordinate guideline policy and programs among medical organizations. In addition, ASIM's research foundation, IMCARE, sponsored a seminar on practice guidelines in June 1990 to which were invited leading representatives of internal medicine subspecialties to inform them about AHCPR and other guideline efforts being conducted around the nation. One of the most significant results of that seminar was the creation of IMCARE's practice guidelines review network.

This network of internists was established to review and provide feedback on guidelines submitted to it for evaluation by a sponsoring organization. Over 200 internists have volunteered to participate in the IMCARE network. Approximately one-third of these physicians are in solo practice, another third are in group practice and the rest are involved in other types of practice settings. As the physicians involved in the IMCARE network will eventually be the "end point" users of practice guidelines, their assessment of and feedback on the guidelines will obviously be extremely useful in ensuring that the guidelines can be used in everyday medical practice. Meetings between representatives of IMCARE and AHCPR have already taken place concerning the use of the network to review some of that agency's guidelines, such as those for BPH and depression, when they are issued. Although its main focus is AHCPR and its products, the IMCARE network will be available for other groups who wish to have their guidelines evaluated by practicing internists.

The next logical step in the guideline process is the incorporation of practice guidelines into medical review criteria. In testimony to the Ways and Means Committee on May 3, 1990, ASIM made a number of recommendations regarding this issue. While we would refer this Committee back to the full text of our statement, ASIM reiterates its strong belief that communication and coordination between AHCPR and HCFA are essential to developing a process for translating practice guidelines into review criteria. We further believe that there should be an opportunity for public comment on the process developed by AHCPR and HCFA and that specific, detailed instructions need to be given to carriers and PROs on applying guidelines to payment and other review decisions. ASIM would also like to point out that the federal government's actions regarding its health care programs are very often adopted by private health insurers. Private insurers have begun to investigate using resource based relative value scales in their reimbursement policies. If the federal government undertakes use of guidelines in its review programs in an open, participatory manner, it can set a beneficial standard for the private sector to follow. Furthermore, if private payors are encouraged to use practice guidelines in a manner consistent with Medicare, this can reduce the "hassle factor" physicians often experience when they encounter conflicting review criteria and processes between Medicare and private insurance programs.

An issue pertinent to the development of practice guidelines arose out of the Omnibus Budget Reconciliation Act of 1990. As the Committee knows, provisions in that Act eliminate almost all Medicare payment for interpretation of electrocardiograms beginning January 1, 1992. Proponents of the OBRA '90 provision contend that EKGs are overutilized and overpaid. To respond to these concerns, ASIM has advocated the use of professionally-developed practice guidelines on the appropriate use of EKGs and the incorporation of such guidelines into payment criteria.

Over the years quite a number of guidelines have been developed involving the performance of electrocardiograms. However, one of the mainstays of ASIM's arguments for guidelines is that they provide a degree of specificity to be useful to practicing physicians in evaluating the appropriateness of procedures and for payers to incorporate into payment criteria. The PPRC has indicated there are few existing guidelines on the proper use of EKGs, especially outpatient EKGs, which can be used to distinguish medically necessary EKGs from those done solely for screening of asymptomatic patients. To be useful to Medicare for payment of EKG interpretation, it is necessary to separate those EKGs done for medically indicated purposes from those that are done for reasons that would not be covered by Medicare, in other words preventive or screening purposes. Perhaps some of the questions that have been raised about overutilization of EKGs, when is an EKG done for screening purposes and when is it done for medically necessary reasons, and how does a practicing physician tell the difference, could be addressed by AHCPR in cooperation with those medical specialties involved with EKGs.

Finally, ASIM wishes to raise with the Committee a matter related to certain guidelines to be used in Medicare's Peer Review Organization program. HCFA is currently in the process of phasing into its PRO network a system called the Uniform Clinical Data Set or UCDS. This UCDS involves the abstraction of particular data from inpatient records which is then run through a computer program according to certain formulae designed to detect quality of care problems. However, HCFA has only now begun to share with the wider medical community the algorithms, or guidelines, used in the computer program to define these quality of care problems. Physicians are more likely to adhere to certain guidelines and modify their behavior accordingly if they believe they or their peers have had an opportunity for input into their development. Many physicians already feel that Medicare's medical necessity and quality review guidelines are developed in secret and imposed on them with little regard for the practice of medicine in "the real world." In addition, the UCDS and its quality algorithms will be used to determine whether some physicians will be able to continue treating Medicare patients or, indeed, continue practicing medicine entirely. Pilot testing of UCDS has found it is overly broad in its identification of

"substandard care" and has the potential for portraying innocent physicians as poor health care providers. In the development of these UCDS quality criteria, HCFA used a panel of experts convened by one peer review organization. Because this did not involve a broad spectrum of medical practitioners, ASIM wonders whether this approach ensures that these guidelines accurately identify substandard care. ASIM believes Congress should monitor closely the implementation of the UCDS to ensure that HCFA involves physicians and other health care providers in the refinement and further development of the UCDS system.

ASIM thanks the members of the subcommittee for their attention to our comments. Your continued interest in and support for practice guidelines and outcomes research, and their reasonable application to review and reimbursement criteria, will contribute to a positive working relationship between physicians and the Medicare program and ensure that patients receive appropriate, effective health care.

PGTEST.491

STATEMENT OF THE RENAL PHYSICIANS ASSOCIATION

The Renal Physicians Association (RPA) is pleased to provided the Ways and Means Subcommittee on Health with a statement for the record for the April 30, 1991 hearing on Medicare quality of care, and outcomes and effectiveness research. An RPA position paper: "Improving Patient Care: A Quality Agenda" is attached. We ask that this paper be considered as part of our statement for the record.

RPA is a national physician organization comprised of over 1500 nephrologists. Our mission is to: 1) insure optimal care under the highest standards of medical practice for patients with renal disease and related disorders; 2) act as a national representative for physicians engaged in the study and management of patients with renal disease and related disorders; and 3) serve as a major resource for the development of national health policy concerning renal disease.

As nephrologists, our statement will concern itself with quality care issues as it relates to the End-Stage Renal Disease (ESRD) program. We reference the Subcommittee to the recently released Institute of Medicine (IOM) report: Kidney Failure and the Federal Government (1991) which provides the most up to-date information on the status of quality care issues as it affects the Medicare ESRD program. The IOM report provides specific recommendations on how to improve the effectiveness and quality of care, and lays out a strategy for the measurement and management of quality in the ESRD program.

The RPA agrees with the IOM's recommendation that: "the Secretary of HHS take all steps necessary to fully implement all functions of the national end-stage renal disease registry called for in OBRA '86..." The registry has the potential to provide valuable information on quality assessment, but to-date the legislative mandate has not been met. Such assessments are necessary to improve quality at the local provider and facility level and ultimately at the national level. Health and Human Services' (HHS) failure to met the mandate seems to have arisen from interagency debates over responsibility. Fulfilling the mandate of OBRA '86 is key to the success of improving the quality of patient care in the Medicare ESRD program.

The RPA supports the following recommendations provided for in the IOM report on quality assessment and assurance. The Health Care Financing Administration (HCFA) should:

1. Evaluate all policies, including reimbursement policies, for their quality impacts on patients.

2. Provide adequate financial support to facilities for quality assurance (QA) by incorporating facility QA costs in reimbursement for both dialysis and transplantation.

3. Coordinate within HCFA the efforts of Health Standards and Quality Bureau, Bureau of Policy Development, and Office of Research and Demonstrations; link existing data bases for the development and operation of ESRD QA oversight systems to relate cost of treatment and quality of care; and integrate the ESRD networks and state surveys in a coherent national QA strategy.

4. Establish an advisory group of nephrology professionals and experts in QA to design, develop, and test validity of ESRD-specific QA systems.

5. Support the regional and national data systems necessary for an effective and ongoing QA system.

6. Support a continuing program of ESRD QA research.

The RPA believes that the move toward improving the quality of care in the ESRD arena has not been fast enough. Fully implementing the OBRA '86 mandate on the national ESRD registry will serve as the major focus of quality efforts for the ESRD program. We hope that the Subcommittee will prod the Secretary of HHS and/or take other necessary actions into seeing that the mandate on the national ESRD registry is met so that effectiveness can be measured and quality improved in the Medicare ESRD program.

The RPA thanks the Subcommittee for its sincere interests in improving care for ESRD patients, and stands ready to provide guidance on this and other ESRD issues.

Attachment.

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IMPROVING PATIENT CARE: A QUALITY AGENDA

The Renal Physicians Association is committed to improving the quality of health care for all Americans. Our ability to assure quality care to all Americans can and needs to be improved. As quality assurance theories and models and definitions of quality care are lending to the debate surrounding the development of a strategic plan for assessing and ensuring the quality of health care, much work remains to be done.

A recent Institute of Medicine (IOM) report, "Medicare: A Strategy for Quality Assurance," has laid much of the groundwork necessary to implement a program to assure the quality of health care for Medicare beneficiaries. And, as Medicare has been the petri dish for changes to the system, with the private sector following close behind (such as the restructuring of hospital payments with the Prospective Payment System (PPS)), a successful quality assurance program for Medicare may very well be an excellent model for adaptation by the private health care sector. This is not to overlook, however, the enormous headway the private sector has made in quality assurance, particularly in the managed care arena.

The IOM report criticized the current Medicare Peer Review Organization (PRO) Program for placing too much emphasis on utilization (and indirectly cost containment) over quality. This focus has limited the Medicare program's ability to improve the quality of patient care while also placing excessive burdens on physicians. At the heart of this major criticism, apparently, lies the concern that assigning a quality assurance program responsibility for controlling utilization and cost will undermine the goals of quality care. The RPA strongly believes that any quality assurance program should be cost-effective to the health care system as a whole, but must focus on quality and improving patient care alone.

Quality, Quality Assessment, and Quality Assurance Defined

Some have found it useful to start with definitions of terms for purposes of discussion. Below is a brief list of definitions to some key terms.

Quality of Care: The IOM report defines quality of care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." Others, such as the congressional Office of Technology Assessment and the Joint Commission on Accreditation of Healthcare Organizations have also similarly defined quality of care. Although all the dimensions of the meaning of quality of care can never be captured in a singular definition, this definition comes fairly close and will undoubtedly be predominantly used by health policy experts in working the debate.

Quality Assessment: Borrowing again from the IOM report, quality assessment may be defined as the "measurement of the technical and interpersonal aspects of health care and the outcomes of that care." Quality assessment is a measurement activity and is the first step in quality assurance.

Quality Assurance: Quality assurance refers to the complete cycle of activities and systems for maintaining the quality of patient care. Quality assurance includes conducting quality assessment, identifying problems in the delivery of care, taking corrective action where necessary, and following up on corrective interventions. One definition many have found useful reads: "a formal and systematic exercise in identifying problems in medical care delivery, designing activities to overcome the problems, and carrying out follow-up monitoring to

ensure that no new problems have been introduced and that corrective steps have been effective."[1]

Quality Assurance Models: Classic vs. Continuous Quality Improvement

Different approaches to quality assurance are undoubtedly necessary for the different settings in which care is provided, such as in a hospital, physician's office, free-standing dialysis facility, or for care given in the home setting, and for different organizational structures such as fee-for-service practices, and managed care organizations.

The classic or traditional quality assurance model and the continuous improvement model (often referred to as the total quality management model) are the two major models of quality assurance we have to-date which offer great promise toward improving the quality of patient care at both the macro and micro level.

The continuous improvement and the traditional model differ from each other in five significant ways. First, the continuous improvement model continually emphasizes the improvement of performance and value even when high levels of performance status appear to be met. With a set performance goal reached, e.g., a particular mortality rate, the traditional approach would cease efforts or shift attention elsewhere. Second, the continuous model stresses evaluation of systems from a consumer perspective, and third, emphasizes their views. The traditional model does neither.

Fourth, the continuous model is designed to improve the overall (average) performance of individuals, much more so than to remove outliers. In industries outside of health care, particularly the Japanese automotive industry, modern quality management focuses on the improvement of the average. In classical forms of quality management, control, and inspection the focus is on the providers and events that are off the average. These older types of methods, improve outlier performance, but keep the remainder of the organization performing at existing levels. While serious problems sometimes stem from outliers, the continuous or total quality improvement theory expounds that problems most often come from average people trapped in flawed processes.

Fifth, and last, the continuous improvement model, vests ultimate responsibility for quality and improvement with the leadership, much more so than the traditional approach, while still emphasizing the personal responsibility of all members to contribute to quality improvement.

The traditional model of quality assurance, with its emphasis on structure, process and outcomes is the more "tried and true" method than the newer model, and provides a strong foundation for many quality assurance efforts. Key to the success of this model, however, will be in the proper application. In recent years, opponents of the traditional model have argued that it is reactive, punitive, and offers nothing but an excessively regulatory (negative) atmosphere. The total quality management (continuous) model has never been fully tested on an isolated health care system. It has, however, proven itself in modern Japanese industry, and has provided the key to their successes in the automotive industry in particular.

Recognizing that no single approach will work for all settings and organizations of care giving, the RPA strongly supports efforts to fully explore, develop, and apply, after careful consideration, both the traditional quality assurance and management approach and the newer model of continuous improvement, i.e., the total quality management theory. The RPA believes that both of these models hold great promise when properly applied in the quality care assurance arena.

Quality Review Process and Criteria

The RPA advocates the establishment of a formalized quality review process which uses current professional knowledge and judgment and the science of medicine as its basis. To do this, a formalized process should, first, be put into place to develop the criteria which will be used for quality review. This process should utilize a diversity of people and expertise and should be guided by the science of medicine. Such criteria should then be field tested and a process should be put into place to review their effectiveness.

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[1] Kathleen Lohr and Robert Brook, "Quality Assurance in Medicine," American Behavioral Scientist, Vol. 27, No. 5 (May/June 1984).

Criteria, against which quality of care can be reviewed, judged or improved fall into three distinct categories. The first, consists of clinical practice guidelines, sometimes also referred to as appropriateness guidelines. The Agency for Health Care Policy and Research within the Public Health Service, created in 1989 has as one of its mandates, the task of developing of practice guidelines for dissemination to the medical community. Patient care evaluation and management criteria is the second category of quality review criteria. This category may include elaborate algorithms and decision trees for specific clinical problems, but may also simply supply descriptions of ways to manage patient problems or evaluate the care rendered to a specific patient. The third category of criteria may be characterized as case-finding screens. These are used to detect potential quality of care problems warranting additional professional review.

Some desirable attributes of such criteria both substantive and structural as developed by the Institute of Medicine staff and which the RPA believes should be present in any criteria developed for quality review include: "clinical adaptability," e.g., for different classes of patients, "flexibility" in which the role of clinical judgment is respected, "concordance," reflecting the consensus of professionals with expertise, and "nonintrusiveness," minimizing inappropriate direct interaction with treating physicians, to name a few.[2]

Overall, the criteria development process should include a convening of a panel of experts, a thorough review of the literature, and a pilot testing of any criteria developed before they are put to general use. And, finally, although the costs of health care should not come into play in a schemata of quality assurance for purposes of purity, the affordability of criteria development and promulgation is a legitimate concern. A careful balance will need to met in the face of scarce resources.

End Stage Renal Disease Program

Through the Social Security Amendments of 1972, the Medicare program extended coverage to all persons suffering from renal failure who were insured under Social Security. From 1965, when the Medicare program was established, until this time, only persons of age 65 or older who had Medicare coverage were eligible for reimbursement for dialysis services. By 1973, when these amendments became effective, Medicare covered 90 percent of Americans with End Stage Renal Disease (ESRD).

History and Quality Mandates of the ESRD Networks

In June 1976, ESRD networks were established through final federal regulation. With the diversity of providers and sites of care involved in the treatment of persons with ESRD, a system to promote effective coordination was sorely needed. Hence, hospitals and other health facilities such as free-standing dialysis units were integrated and organized into area networks, in an attempt to effectively assure the delivery of needed ESRD care. Subsequently, the End Stage Renal Disease Amendments of 1978 were enacted authorizing the formal establishment of ESRD network areas and network organizations using criteria the Secretary finds appropriate to assure the effective and efficient administration of ESRD program benefits.

The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA '85), enacted in April 1986, further requires the Secretary of the Department of Health and Human Services (HHS) to maintain the ESRD network organizations and specifically not to merge them into other organizations or entities. This statute permitted the Secretary to consolidate the network organizations, but only if such consolidation did not result in fewer than 14 organizations nationally. At that time, 32 ESRD networks existed. In April 1986, the Secretary put into effect final regulations which consolidated the existing 32 networks to 14, and set forth the geographic areas of the new network organizations under the ESRD program. Later, the Omnibus Budget Reconciliation Act of 1986 (OBRA '86), enacted in October 1986, required the Secretary to establish at least 17 ESRD network areas.

OBRA '86 also had several other key provisions affecting the ESRD program and specifically relating to the quality of patient care. These provisions were put into final regulation in January 1988. The law requires each ESRD network organization to:

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[2] Institute of Medicine, "Medicare: A Strategy for Quality Assurance," Vol. I (1990), pages 327-328.

- appoint a network council of renal dialysis and transplant facilities located in each area and a medical review board with responsibility for evaluating the quality and appropriateness of care delivered to ESRD patients;
- report to the Secretary on facilities and providers that are not rendering appropriate medical care;
- implement a procedure for evaluating and resolving patient grievances;
- conduct onsite reviews of individual ESRD facilities and providers as necessary, as determined by the Secretary or the medical review board using standards of care established by the network organization to assure proper medical care;
- identify in their annual reports to the Health Care Financing Administration (HCFA) those facilities that consistently fail to follow the recommendations of the medical review board;
- collect, validate, and analyze all ESRD program data as needed to prepare their annual reports to HCFA, and for the Secretary's report to Congress on the ESRD program, and to assure the maintenance of the national ESRD data registry; and
- follow the recommendations of the medical review board. Providers are required to follow such recommendations as well.

The final regulations implementing this section of OBRA '86, further require the network organizations to develop criteria and standards relating to the quality and appropriateness of patient care. The RPA fully supports the mandates of the ESRD network organizations toward assuring the quality of patient care, and believes that when a strategic quality assurance program is undertaken, it should build on this existing system. Funding should be appropriate to meet these needs.

History and Quality Mandates of the National Registry

OBRA '86 also requires the Secretary to establish a national ESRD patient registry for the purpose of assembling and analyzing the data reported by the network organizations, transplant centers, and other sources on all ESRD patients in a manner that will permit:

- an identification of the economic impact, cost-effectiveness, and medical efficacy of alternative modalities of treatment;
- an evaluation with respect to the most appropriate allocation of resources for the treatment and research into the cause of ESRD;
- the determination of patient mortality and morbidity rates, and trends in such rates, and other indices of quality of care; and
- the preparation of annual report to Congress, and other analyses relating to the treatment of and management of ESRD which will assist Congress in evaluating the ESRD program.

The Secretary is additionally responsible for:

- providing for the coordination of data collection activities, and consolidation of existing ESRD data systems, as is necessary to achieve the purpose of the registry;
- determining the appropriate place of the registry; and
- providing for the appointment of a professional advisory group to assist the Secretary in the formulation of policies and procedures relevant to the management of the registry.

The national ESRD registry, also now officially referred to as the United States Renal Data System (USRDS) became operational in early 1989. The Secretary gave operational responsibility for the USRDS to the National Institutes of Health (NIH) which competitively awarded a contract to the Urban Institute to serve as a coordinating center and to build the data system and conduct research. Funding for the USRDS comes out of the NIH's National Institute of Diabetes and Digestive and Kidney Diseases' (NIDDK) budget.

The professional advisory group on the registry was established in early 1990, but has not formally held any meetings. The group, the ESRD Data Advisory Committee, is a combined HCFA/NIDDK effort.

The USRDS has the potential to provide valuable information on quality assessment, but to-date the legislative mandate has not been fully met. NIH has indicated that quality issues are not within the scope of their mission, and HCFA has only proposed two time-limited studies focusing on cost issues alone to implement the legislative initiative. The missing element is the integration of quality assessment and assurance activities with research activities including cost issues and data collection efforts.

The importance of the work of the USRDS cannot be stressed enough in the furtherance of improving the quality of patient care. With research (medical, effectiveness, outcomes, etc.), the collection and analyses of data, and dissemination of results to the provider community including local providers, facilities and transplant center, and the networks, the quality of patient care can be improved. USRDS efforts can now also be enhanced by coordinating activities with the new Agency for Health Care Policy and Research, within the Public Health Service, established through OBRA '89 with responsibility for the study on the appropriateness of medical treatments and the development and dissemination of practice guidelines based on such research. Here, educating physicians and other providers, required of the Secretary in OBRA '89 on the results such research will be crucial in improving the quality of care.

The entire quality effort will take the involvement of all concerned parties -- physicians, and other providers, insurers, consumers, and national and local governments -- to be successful. This includes everyone's cooperation and participation in all phases of a quality improvement plan -- through development, implementation and education. Responsibility for quality improvement must be shared, but with national direction and funding, and regional implementation. Again, coordination is key.

Conclusion

The Renal Physicians Association:

1. is committed to improving the quality of patient care.

2. believes that any quality assurance program should be cost-effective for the health care system, but must focus on quality alone as distinct from utilization and cost control.

3. agrees with the findings, conclusions, and recommendations of the IOM report, "Medicare: A Strategy for Quality Assurance," and recommends that Congress enact legislation which parallels the IOM's approach to improving patient care. Such legislation should not empower HCFA with sole responsibility for the quality assurance effort (unless its mandate and program structure are significantly altered, separating cost and quality efforts, and outside oversight is required) as HCFA's responsibility lies with cost containment, and as it may also violate that section (1801) of the Social Security Act which essentially prohibits Medicare from interfering with the practice of medicine.

4. strongly supports efforts to more fully explore, develop, and properly apply the two major and promising models of quality assurance to-date -- the traditional and the continuous model -- while recognizing that no single approach is suitable for all settings and organizations of care giving.

5. advocates the establishment of a formalized quality review process which utilizes current professional knowledge and the science of medicine and professional judgment as its basis; and a formalized process to develop the criteria which will be

used for quality review and against which the quality of care can be judged and improved.

6. recommends that reports on aggregate data and quality assessment measures be collected by the U.S. Renal Data System (ESRD Registry), and be provided to ESRD networks and providers to facilitate the implementation of local quality assessment and assurance programs.

7. supports research (and funding) into quality assessment tools and methods, including the need for development and testing, and into techniques of feedback to the provider community.

8. supports educational activities to change provider behavior where necessary.

9. supports the structure of the ESRD networks, and is committed to modifying, enhancing and expanding the network functions to fulfill the principles articulated.

10. is committed to ensuring that the full mandate of the ESRD Registry (U.S. Renal Data System (USRDS)) is met, and recommends building on its existing organization and functional activities towards the quality and cost analyses as outlined above.

11. is committed to evaluation of the effectiveness and costs of the various quality assessment and assurance programs and tools.

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